REGULATORY FAILURE: MUST AMERICA LIVE WITH UNSAFE FOOD?

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MARCH 12, 2008

Serial No. 110–99

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WITNESSES

SUBMITTED MATERIAL

REGULATORY FAILURE: MUST AMERICA LIVE WITH UNSAFE FOOD?

WEDNESDAY, MARCH 12, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:08 a.m., in room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, DeGette, Melancon, Waxman, Green, Schakowsky, Dingell (ex officio), Shimkus, Whitfield, Walden, Burgess, and Barton (ex officio).

Staff present: John Sopko, David Nelson, Kevin Barstow, Richard Wilfong, Scott Schloegel, Kyle Chapman, Krista Carpenter, and Alan Slobodin.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order. Today we have a hearing entitled "Regulatory Failure: Must America Live With Unsafe Food?" Each Member will be recognized for an opening statement. I will begin. Since the 110th Congress began in January 2007, this subcommittee has been investigating the Food and Drug Administration's ability to protect Americans from unsafe food. This is the subcommittee's sixth hearing regarding the safety and security of the nation's food supply. While the previous five hearings have focused on a variety of topics including companies who have produced contaminated food, unsafe food imports, and the ability of the FDA and USDA to protect our Nation's food supply, today's hearing will focus on what steps the regulators have taken or need to take in order to ensure the safety of our food supply.

Since our investigation began 14 months ago, there have been at least 163 recalls and health alerts associated with FDA-regulated products. Despite USDA's hefty budget and large inspection force, it too is not immune from problems. Since 2007, there have been at least 67 meat recalls totaling 180 million pounds of meat. There has also been an alarming jump in the number of recalls and illnesses associated with E. coli-contaminated meat. In 2007 alone, there were 20 recalls of meat products due to being tainted with the deadly pathogen E. coli. These recall efforts affected about 33 million pounds of meat. This compares with just 8 recalls and just over 155,000 pounds of meat in 2006 due to E. coli.

These numbers alone indicate that there is a serious increasing problem with our food safety system. Still, there is even greater support for this assertion. The Centers for Disease Control and Prevention now estimate that there are 76 million cases of food borne illnesses every year in the United States. These illnesses result in an estimated 5,000 deaths and 325,000 hospitalizations. It is clear that our food safety system is broken. We must address this stark reality and remedy this dire situation.

The subcommittee has had the unfortunate experience of watching firms that have sold contaminated food falsely assure the American public that the safety problems have been solved only to learn that yet another outbreak or recall has occurred within a few months. Cargill and Dole both are repeat offenders and ConAgra has had three recalls this past year. On Monday the newly reopened Castleberry plant, whose parent company witness testified 2 weeks ago that Castleberry had learned its lesson from the botulism contamination, but on Monday they were shut down by FDA and USDA's Food Safety Inspection Service again. This shut-down was due to processing violations that could lead to pathogen contamination.

Today we will hear from the company responsible for perhaps the most notorious recall over the past year. Steven Mendell, the President of Westland/Hallmark Meat Company, will testify regarding his company's recall of more than 143 million pounds of raw and frozen beef products. This was the largest meat recall in the history of the United States. The most troubling aspect of this recall is that approximately 50 million pounds of the beef were sold to the National School Lunch Program and other Federal nutritional programs for the poor and elderly. Thankfully, to date there have been no reported illnesses associated with this meat.

Mr. Mendell was invited to testify at the subcommittee's previous food safety hearing on February 26 regarding the circumstances surrounding his company's recall. Despite extensive efforts by committee staff to reach out to Mr. Mendell, he avoided contact with the committee staff and chose not to appear at the February 26 hearing. Because of Mr. Mendell's unwillingness to appear voluntarily, the subcommittee was forced to issue a subpoena to comply Mr. Mendell's testimony here today. We look forward to finally hearing from him.

Throughout our prior five food safety hearings, one thing has been evident. There are increasing concerns about the safety of the nation's food supply and it is necessary to utilize more technology to make our food supply safer. Due to the interest raised by our last hearing, today we will explore one such technology: food irradiation. Food irradiation is a technology which destroys organisms that cause foodborne illnesses. Proponents of food irradiation believe it is a safe and effective technology that can guarantee the safety of food. Some claim irradiation is the only sensible kill step for leafy greens and meats. Others, such as the president of Dole, claimed last month that it was not workable and harmed fresh produce.

Today, we will hear testimony from Dr. Dennis Olson, a Professor of Animal Science at Iowa State University and an expert on the use of food irradiation. Dr. Olson will testify regarding the po-

tential benefits of irradiation. We will also hear from Mr. Daniel Wegman, the CEO of Wegmans Food Markets. As a CEO of a supermarket chain that sells irradiated meat, Mr. Wegman will discuss why his company chooses to offer irradiated products to its consumers. While food irradiation will be the only technology discussed at this hearing, the committee is also exploring other food safety technologies. We hope to examine these as our food safety investigation continues.

We will also hear today from Target Corporation. In November, Target sent a formal letter to USDA requesting approval for a label that would alert consumers that certain meat products Target sells are packaged in an atmosphere containing carbon monoxide. Amazingly, USDA did not approve the label. I look forward to hearing why USDA would not approve such a label, and I look forward to hearing what other efforts Target Corporation has made to inform their consumers of the carbon monoxide packaged meat they sell. Finally, we will hear from two primary regulators of our food supply, the FDA and the USDA. Dr. Stephen Sundlof, the Director of the Center for Food Safety and Applied Nutrition at FDA, and Dr. Richard Raymond, the Under Secretary for Food Safety at USDA, are here. Each will testify about the steps their agencies have taken or need to take to ensure the safety of our nation's food supply.

As I stated previously, today's hearing is our sixth hearing regarding the safety and security of our nation's food supply, and it probably will not be our last. The American public can be assured that we will continue to hold as many hearings as necessary to fix our country's broken food safety system. When we have companies, government agencies, or individuals before this committee, we expect them to follow through on the promises they make. We will do follow-up and we will bring them back before the committee to account for any failures on the promises they made to us and the American people. That concludes my opening statement.

[The prepared statement of Hon. Bart Stupak follows:]

STATEMENT OF HON. BART STUPAK

Since the 110th Congress began in January 2007, this subcommittee has been investigating the Food and Drug Administration's ability to protect Americans from unsafe food. This is the Subcommittee's sixth hearing regarding the Safety and Security of the Nation's food supply. While the previous five hearings have focused on a variety of topics including companies who have produced contaminated food, unsafe food imports, and the ability of the FDA and USDA to protect our Nation's food supply, today's hearing will focus on what steps the regulators have taken or need to take in order to ensure the safety of our food supply.

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Today, we will hear testimony from Dr. Dennis Olson, a Professor of Animal Science at Iowa State University and an expert on the use of food irradiation. Dr. Olson will testify regarding the potential benefits of irradiation. We will also hear from Mr. Daniel Wegman, the CEO of Wegmans Food Markets. As a CEO of a supermarket chain that sells irradiated meat, Mr. Wegman will discuss why his company chooses to offer irradiated products to its customers. While food irradiation will be the only technology discussed at this hearing, the Committee is also exploring other food safety technologies. We hope to examine these as our food safety investigation continues.

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Finally, we will hear from the two primary regulators of our food supply, the FDA and USDA. Dr. Stephen Sundlof, the Director of the Center for Food Safety and Applied Nutrition at FDA, and Dr. Richard Raymond, the Under Secretary for Food Safety at USDA, are here. Each will testify about the steps their agencies have taken or need to take to ensure the safety of this Nation's food supply.

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Mr. STUPAK. I would now like to turn to my friend, Ranking Member Mr. John Shimkus, for an opening statement. I would just caution everyone, it looks like we are going to have a vote here pretty quick, and we expect a number of procedural votes on the floor today. Tempers flare a little bit. It got a little late last night, and so I think we might be back and forth which disrupts our hearing, but I appreciate everyone's patience and we will try to get back and forth forthwith. There is also another hearing going on in the Energy and Commerce Committee. Mr. Shimkus, opening statement, sir?

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman. I appreciate the hearing. I believe that this hearing will serve two purposes. First, this hearing follows up on the hearing we held on February 26, and includes some key witnesses, including representatives from USDA and FDA not present at the earlier hearing. Second, this hearing highlights issues arising from the largest beef recall in U.S. history and focuses on advances in food technology, in particular the use of irradiation, and how this kill step could be added in food processing systems to increase the safety of our food supply.

Of course, I am eager to hear testimony from Mr. Mendell, the CEO of Hallmark/Westland Meat Packing Company, and I hope that he can answer the questions we all have concerning the illegal and dangerous practices committed at his plant that we witnessed at the last hearing. On the same note, I am also eager to hear from Dr. Raymond, the Director of FSIS at the USDA and hope that he can answer questions concerning the conduct, responsibilities, and actions of USDA inspectors present at the plant as well as those stationed at other meat processing facilities across America.

At some point during this year of food safety investigations, committee staff began to believe that the food safety model proposed may serve as an archetype for FDA. However, with over 60 meat recalls last year and with increase in reports of E. coli in meat, committee staffers are beginning to question whether or not the inspector based food safety model works as well as previously thought. The bottom line is, does having an inspector present at every meat processing plant actually decrease the likelihood of the presence of this pathogens in a finished product? If the inspectors cannot see the pathogens, what good does the physical inspection of that product do? Would the inclusion of a kill step like irradiation and more end product testing be a better use of our limited resources? These are the kinds of questions that these recent recalls and outbreaks raise, and we want to try to get some answers today.

I look forward to hearing from Dr. Olson and Mr. Wegman about the advances in irradiation and the effective use of this technology. Former committee chairman Bliley requested that GAO complete a report on the beneficial use of irradiation on food products which was published in 2000. The report concluded that scientific studies conducted by public and private researchers worldwide over the past 50 years support the benefits of food irradiation while indicating minimal potential risk. However, when the report was pub-

lished consumer acceptance of irradiation food products was extremely low. I look forward to Mr. Wegman describing his experience with consumer acceptances of irradiation food process. If consumer acceptance remains low but the science behind irradiation confirms that it kills these dangerous pathogens and increases the safety of our food, I want to know what can be done to improve consumer acceptance of this technology and what role, if any, FDA or USDA has to help convey that message.

Lastly, Dr. Sundlof, the FDA Director of the Center for Food Safety and Applied Nutrition, is here to answer some pending regulatory questions surrounding numerous aspects of food safety including the issuance of voluntary guidelines on leafy greens to private industry. The FDA's response to botulism scares at the Castleberry and New Era plants and discrepancies in the microbial testing results at the ConAgra plant in Sylvester, Georgia, and the ongoing concerns over imported seafood.

Today is about getting answers for the American people. I thank our witnesses for coming, and I look forward to discussing this vital policy issues. I tried to go fast, Mr. Chairman. Thank you.

Mr. STUPAK. You did, and I appreciate that. Mr. Dingell for an opening statement, please. We still have plenty of time, 10 minutes, on the floor yet.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Thank you. I commend you for holding today's hearing, and for your leadership in the committee's efforts to protect our Nation's food supply. You have been providing superb leadership in this matter and the Nation owes you great gratitude. Those who heard the testimony at our first food safety hearing of the parents of children who became sick or seriously injured from contaminated food understand how important these efforts are. So what have we learned from our work so far? First of all, CEOs of major food companies testified they will do better but we only find that they have not. Second, food and drug employees and our own staff investigators tell us that the FDA has little or no control over the quality of the food entering the United States because the agency is understaffed, underfunded, and lacks the technological capabilities that are necessary to address its problems.

The FDA rewards headquarters bureaucrats with bonuses, scandalously so, while they systematically starve their field inspection and laboratory forces. The new FDA food czar, its enforcement chief, and the commissioner tell us that FDA can do more with less, a patently false claim that I have heard for 30 years, and very frankly I want to tell you this is probably one of the finest fairy tales I have heard, and I have been told it every day that I have talked to the heads of FDA and it is always proven to be false and probably deceitful and possibly actively so. FDA promises new technologies, yet they have delayed the deployment of irradiation, a technology that some experts say promises truly effective cure mechanisms for the pathogens that contaminate our food.

Today we will have a chance to question those same regulators who are responsible for the safety of American foods. We will ex-

pect straight answers about what they intend to do and how they intend to halt the illness and economic waste associated with 168 recalls that have occurred since we began the inquiry last year. We might also inquire how many more recalls should have occurred that did in fact not occur. I am particularly pleased that Mr. Mendell of Westland/Hallmark Meat Packing is appearing before us today. I hope that he has learned that this committee has an adage of some age that it is important that our witnesses understand there is an easy way and there is a hard way to answer our questions and cooperate with the committee. Either way this committee has and will find out the truth, and the truth today that we want to know is how much money he made from illegally slaughtering so-called downer cows—cows so sick or injured that they could not walk or stand, cows universally viewed as potentially dangerous carriers of mad cow disease, and how he participated in a program which denied safety to the American public with regard to their food supply.

The good news, however, is that no mad cow disease has yet been found, although the incubation period for this disease might be up to 20 years or longer for humans. Nevertheless, Mr. Mendell's firm has cost school districts and other companies greatly in replacing meat that was recalled. I am curious what Mr. Raymond of the U.S. Department of Agriculture is going to tell us that his inspectors were doing in the California plant while the downer cows were forced into the kill boxes. He must also tell us why he refuses to allow a major retail operator the right to tell his consumers how their meat is prepared and how their meat is preserved or treated. I am equally curious to hear how Mr. Sundlof of FDA will explain what he intends to do about the Office of Pre-Market Approval.

This body appears to have botched the generally recognized safe, or GRS, applications for carbon monoxide packaging for meat and fish, yet the records are all mysteriously lost of how their meat review after the committee began its inquiries, and we will ask for the production of those papers. In closing, I want to remind colleagues that at our first hearing we heard the dramatic testimony of a mother of a 2-year-old who needed a kidney transplant because the spinach that the child ate was contaminated with E. coli. At our last hearing, Mr. Sundlof's predecessor told us that the mandatory regulations he prepared were ignored by Health and Human Services in the confusing surrounding melamine imports. I am curious to hear what Mr. Sundlof has done to resurrect these regulations that could protect other children from similar fate. I also will want to know what his resources are and what the agency intends to do to both get the resources and to reform its practices to protect the American people.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Dingell. Mr. Barton for an opening statement, please. We still have time before we run to the floor to vote.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Stupak and Chairman Dingell, for holding this hearing on the food safety. I am very appreciative of

what you are trying to do. There is no daylight between the Republicans and the Democrats on the issue of food safety for the American people. Americans have the right to know which people are raising their food, harvesting their food, processing it, packaging it, delivering it, selling it, and inspecting it. We are committed, we on the Republican side, to working on a bipartisan basis. Once we have completed our investigation there are legislative things that need to be done we will work on a bipartisan basis to enact new legislation in this area.

Today we have several witnesses here that we are anxious to hear from. I especially want to hear from Dr. Raymond at the United States Department of Agriculture. I think there should be some questions asked about what the role of the inspectors for the USDA were at Hallmark/Westland, and why they apparently weren't able to catch what was going on before the famous videotape was released. I also would like to hear a little bit more about what a witness at our last hearing called an "up-tick" on the presence of E. coli in the meat and the resulting increase in the number of the recalls.

I would also like to hear from Dr. Raymond explaining the process that the USDA goes through when deciding whether to initiate a recall or not and how it affects the consumers and the businesses as well as the customers involved. So I think we have a good witness list, and we are ready to participate as soon as we finish with the important work on the floor. There is also a hearing going on in the committee upstairs of Energy and Air Quality on Pipeline Safety so some of us will be going back and forth. Thank you, Mr. Stupak, and welcome our witnesses. We are ready to go to work.

[The prepared statement of Hon. Joe Barton follows:]

STATEMENT OF HON. JOE BARTON

Thank you, Chairman Stupak. Let me note at the outset that the Committee's oversight of food safety and its efforts to gather new information about problems and solutions are a valuable application of our jurisdiction, and I strongly support this mission. Americans have to know that the people who raise, harvest, process, package, deliver, sell and inspect what we eat are actually protecting the public from being sickened and killed by our food. As these hearings unfold, I'm committed to working with you and writing bipartisan legislation to ensure that buying and consuming food in this country is a safe process. There should be no daylight between Republicans and Democrats on this.

Today we have the right witnesses here to answer some of the questions raised at our last food-safety hearing.

I am particularly anxious to hear the testimony of Dr. Raymond from the USDA. I hope that he is prepared to explain what his inspectors at the Hallmark Westland Meat Plant were doing and whether those questionable actions are prevalent in other USDA-inspected meat processing facilities. I certainly hope the answer is no.

I also hope that he can help us identify the source of what a witness at the last hearing called an "uptick" in the presence of e-coli in meat and the resulting increase in number of meat recalls. Lastly I hope that Dr. Raymond can explain the USDA recall process and how it affects both the consumer and the businesses involved. Several witnesses at the last hearing indicated that the latest recall of 143 million pounds of meat may have been an over-reaction and a misuse of USDA resources. I want to know if that assessment is valid.

Secondly, I am anxious to hear from the witnesses on the second panel concerning their knowledge and use of irradiation on food products, including meat and produce. The inclusion of irradiation to eliminate the contamination of food is one that has been widely endorsed for years. In fact, the former Chairman of this Committee, Mr. Bliley, requested that GAO complete a report on the benefits and risk of irradiation which was published in 2000.

The report concluded that a half-century's worth of research conducted by government and private scientists worldwide recognize and support the benefits of food irradiation and indicate that any potential risk is marginal. Back in 2000, the report noted that the major purchasers of irradiated foods were health care and food service establishments, which purchased them specifically to reduce the threat of foodborne illness. But, concerns on the part of food processors, retailers, and others about consumer acceptance of irradiated foods have limited their availability to date. We all know how easy it is for activists to sow fear, but real people are getting sick from bad food and the politics of fear won't make them well again. I think it's finally time to tell the public what we know about a food-processing technique that will keep them from getting sick.

Back in 2000, FDA officials, including the Director of the Division of Product Policy, Center for Food Safety and Applied Nutrition, generally agreed with the findings presented in the GAO report. The question I have for Dr. Sundlof, the new Director of CFSAN, is what is the status of the recommended or mandatory use of irradiation by FDA? What is the FDA's official stance on this technology? If already FDA approved, then why aren't more processors using this technology?

Lastly, I look forward to hearing the testimony of all our witnesses and in making progress on securing the safety of our food supply. Thank you Chairman.

Mr. STUPAK. Thank you, Mr. Barton, and a good job on Washington Journal today.

Mr. BARTON. Yes, I said some nice things about you so I hope you remember that.

Mr. STUPAK. Mr. Waxman, we still have some time if you want to get yours in. I am not sure if we are going to have one or two votes but why don't you start, and I think we have most of the openings done. When we come back, we will be able to move right in to testimony.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Mr. Chairman, I am pleased you are holding these series of hearings on food safety. It is so important. The American people assume it is a given that when they sit down to eat, the food is going to be safe. But we are hearing reports every single day about another contaminated meat or produce item, and the public is getting very, very anxious about it. I was pleased that Mr. Barton talked about doing something on a bipartisan basis. I hope he will work with us to accomplish the goal of assuring the American people that food is safe. I want to focus on one issue. Several years ago there was a story about E. coli in spinach and that raised a lot of concerns. Representative DeLauro and I decided to do an evaluation of what was going on with the produce, and today we are issuing our report.

The investigation reveals, I fear, a system that is incapable of preventing another outbreak in fresh produce. The findings of the report are stark. FDA is supposed to inspect every year. Instead they go every couple of years. When they find problems, and they are common, they don't make sure that the problems are corrected. Over 6 years of records we reviewed, FDA did not take a single meaningful enforcement action, not a single warning letter, seizure or injunction. We looked at this company called Natural Selections. That was the firm implicated in the 2006 outbreak of E. coli in spinach. FDA inspectors found multiple problems with that company and still no enforcement actions. Shockingly, the FDA cur-

rently has no real authority to require firms to grant the agency access to records, so they can't get the records, they don't go for the inspections, they don't find out what is happening, and then lo and behold, we get an outbreak of problems.

This investigation revealed these serious problems with the FDA's system for protecting fresh produce. Some of this is because of lack of resources. Some of it is because of lack of authority at the FDA. And I must say I have been dismayed at the Bush Administration's failure to demand additional resources and to revamp the FDA itself to make sure they do a better job. I commend you for holding this hearing, and I look forward to this committee working on a bipartisan basis because we owe it to the American people to assure them with confidence that their food is safe. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Waxman. That appears to be the end of the opening statements. We are going to recess for 15, 20 minutes. We are not sure if we have one or two votes. We will be back right after votes. We stand in recess.

[Recess.]

Mr. STUPAK. The committee will come to order. I am sorry about the votes. It is going to be a disruptive day on the floor and 1 vote turned into about 4. The ranking member and I, Mr. Shimkus and I, have agreed that if they do any more of these votes where it is just to adjourn and no other votes, we are not going to go back. We want to get this hearing in. We are just going to stay and march through here. Before we left, I know Mr. Waxman wanted to submit this. I am going to ask unanimous consent to submit for the record Committee on Oversight and Government Reform Majority Staff report March, 2008, FDA and the Fresh Spinach Safety, prepared by Mr. Waxman. Without objection be made part of his opening statement. Ms. DeGette, opening statement, if you would, please.

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. Thank you, Mr. Chairman. I would ask unanimous consent to put my full opening statement in the record. And I would just note that I am happy that our witnesses are here with us today. I am eager to hear an explanation of what happened in this situation on the heels of the hearing a couple of weeks ago. And in particular a couple of issues that I am interested in hearing about is how we can set up a system of traceability, which is a law I have been sponsoring for some years, and also if a mandatory recall system would help either get the product back or preferably to deter conduct like this. So with that, Mr. Chairman, I will submit and I yield back.

[The prepared statement of Hon. Diana DeGette follows:]

STATEMENT OF HON. DIANA DEGETTE

Thank you, Mr. Chairman.

I want to applaud you for holding this hearing today, and for the comprehensive investigation into food safety throughout your tenure as Chair of this subcommittee. Nothing is more important than the safety of our food.

Today we continue our efforts to see what the private sector can do to help ensure that the food we put on our tables each day is as safe as it can possibly be. I think we all understand that restoring the confidence of the American consumer is simply not something the government can do alone.

Two weeks ago we heard from the CEOs of some of the largest food processors in the country, some of whom were involved in outbreaks of foodborne illnesses.

Many of us were dismayed that these CEOs, as they often do, came before us and simply apologized for the outbreaks. But our intent on this committee is not to receive apologies but to find out exactly what happened, why it happened, and what is being done to make sure it doesn't happen again.

Several witnesses updated us on their plans to improve their internal processes for this or that product. But that's not good enough. Some of these companies have cleaned up the mess and implemented best practices following a recall, only to have yet another outbreak in a completely different product line a few months later. And then another, and then another.

Ladies and gentlemen what we need on food safety is dramatic overhaul, not tinkering around the edges, in both the public and private sector.

But while the testimony of these CEOs was far from adequate, I do want to applaud them for testifying in the first place. Our witness today has not been as cooperative.

One of the fundamental roles of Congress is to conduct oversight. That oversight hinges on the ability to gather information on behalf of the American people, shine light on problems, and if necessary develop policy-based solutions.

But, we cannot perform this function when information is being withheld. Mr. Mendell, you were contacted by this committee on numerous occasions to request that you appear before us.

Just last month, your company was involved in the biggest meat recall in the history of this nation, after shocking undercover video footage at your plant was released.

Your company acted responsibly and ordered a recall, but that is not the end of the story. The American people have the right to know what happened.

As you know, this committee has been looking into cracks in the food safety system for quite some time now. I would think that the biggest recall in history is something that we should investigate further.

But when this committee tried to invite you to testify, we did not hear back. In fact after 15 phone calls, we did not get a response from you, your counsel, or your company.

We were forced to issue a subpoena to compel your testimony this morning. I hope you will be more cooperative with us today so we can get to the bottom of this.

One of the things I hope you are forthcoming about is your company's system of tracing the meat products you sold. We have all heard the media reports that some of the recalled meat was sent to schools around the country, including to Jefferson County Schools near my district in Colorado. There are also reports that meat was sent to large wholesalers and retailers, who presumably distribute across the country.

The fact is, we can never really know where all of the meat was sent because there is no effective traceability system in place in the United States.

For years I have introduced legislation, H.R. 3485, to set up a system to trace food products from the farm to the fork. Right now there is no quick, reliable way to find out where food was produced and to where it has been sent.

In the event of an outbreak of illness, or in this case, the introduction of sick cattle into the food supply, a traceability system would allow us to quickly identify the source, inform businesses along the supply chain, cease distribution of other tainted products, and notify potential consumers and business owners who may have this food in their homes, restaurants, and on their store shelves.

Some companies already have an effective tracing system; indeed advances in technology make it achievable and cost effective nationwide.

In addition to traceback, I'd like to ask the USDA and FDA about another piece of legislation I've sponsored, that would give them each the ability to recall tainted food, an authority they lack right now.

In this case, it seems that Westland/Hallmark issued a recall immediately upon seeing the video we witnessed today, showing irrefutable and sickening evidence of its employees not only mistreating sick animals, but putting them into the nation's food supply.

Would a voluntary recall have occurred without such convincing evidence? I think the government should have the authority to act in the case that a company does not act quickly enough.

Obviously we should focus our efforts on preventing contamination in the first place, but we also need to have better procedures in place to deal with an outbreak, especially with regards to recalling and tracing food products.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you. That concludes the statements by members of the subcommittee. I will call our first witness to come forward. On our first panel is Mr. Steve Mendell, President of Hallmark/Westland Meat Company. It is the policy of this subcommittee to take all testimony under oath. Please be advised, sir, that you have the right under the rules of the House to be advised by counsel during the testimony. Do you wish to be represented by counsel? Mr. Mendell, do you wish to be represented by counsel? OK. We are going to ask you to turn it on, and we recognize our former colleague Asa Hutchinson may be assisting you in this testimony, is that correct?

Mr. HUTCHINSON. That is correct.

[Witness sworn.]

Mr. STUPAK. Let the record reflect that the witness replied in the affirmative. Mr. Mendell is now under oath. Before we begin, one of the reasons why we are here is this video that was played, so before we hear from our witness I would like to show a brief video that was produced by the Humane Society as part of their undercover investigation of the Hallmark/Westland Corporation's slaughtering house operation. We invited you, Mr. Mendell, to appear at our last hearing but for some reason you declined to appear. At our last hearing we showed this video, which is the basis for many of the members' questions, and I want to be sure you have had a chance to see it so you can accurately reflect upon our questions. Following the video, we will hear your opening statement. Before we run the video, as I did last time, I want to caution viewers it is quite graphic. Kyle, would you run the video for us, please?

[Video.]

Mr. STUPAK. OK. We will now hear a 5-minute opening statement from Mr. Mendell. Mr. Mendell, you may submit a longer statement for the record, and please begin, sir.

STATEMENT OF STEVE MENDELL, PRESIDENT, HALLMARK/WESTLAND MEAT COMPANY

Mr. MENDELL. Thank you, Mr. Chairman. As you stated, I am the President of Hallmark/Westland Meat Company. The company is in the business of harvesting and processing beef under the Federal Meat Inspection Act. Until a few weeks ago, my company was viewed as having an excellent record in the areas of humane handling and food safety. We took pride in this record. In early February, I was contacted by a Washington Post reporter. The reporter sent me an excerpt of the video taken by the Humane Society. I was shocked, I was horrified, and I was sickened. I agreed that the actions shown in the video were inhumane and completely reprehensible. The actions were a blatant violation of the company policies and procedures. These policies and procedures were not just documents but were implemented through training and regular compliance audits. The company has always been committed to best practices when it comes to humane handling and food safety.

In 2007, the company passed 17 outside audits and twelve additional internal audits. The company has been regularly audited by the Audit, Review and Compliance Branch of USDA. The company has also been regularly audited by Silliker, as well as other inde-

pendent third-party auditors. I ask that these reports be made part of the record.

Mr. STUPAK. I won't accept them right now but we will ask some questions when you are done, and then maybe they can be part of it, but please continue with your statement.

Mr. MENDELL. The company received the highest scores in the areas of humane handling and food safety. From the video I saw, two employees blatantly violated those policies and procedures. Our company has a zero tolerance policy for inhumane treatment. The video was apparently taken in October or November of '07. Had I known about the employees' actions sooner, I would have terminated the employees on the spot. I want to emphasize though the activities shown on the video that I saw are not food safety issues. The cows shown in the video could not walk, were designated to be euthanized and were not put into commerce. There is a question about the last cow I saw on that tape because I had not seen that tape. These cows would not have passed USDA inspection to enter the processing line.

I also want to emphasize that it would be financial suicide for a company to harvest or process a cow that it believes to be sick. Generally, the company does not pay suppliers for the cost of a cow deemed unfit for human consumption. Therefore, there are no financial incentives to bypass regulations. It is for this reason that the company would have no interest in processing a non-ambulatory cow. In audit after audit, the USDA, and other outside auditors, and our internal audits found negative test results for the presence of E. coli 157 and salmonella. The audits also reported that the company with complying with humane handling laws and company policies. In February, my management team and I examined what steps we could take to ensure that no inhumane handling occurred.

We reviewed our policies which are in accordance with the guidelines of Dr. Temple Grandin, a world-renowned expert in humane handling practices. We confirmed that the two fired employees, as well as the Humane Society employee, had participated in extensive training and retraining. We hired Dr. Erica Voogood to ensure that we had best practices. We hired all new pen employees and a new pen manager. We installed 17 cameras that would videotape unloading, pens and chutes areas so we could monitor compliance with humane handling practices. We were taking all the steps we could to ensure for USDA, our customers, and the public that the inhumane handling shown in the video would never recur. I then received a call from USDA indicating that they had a second video—that they had received a second video, a video which I asked to see, which was not provided and which I have never seen. At the urging of the USDA, however, our company voluntarily recalled all products containing any trace amounts of beef harvested by our company for the last 2 years. Our company is now the subject of the largest meat recall in U.S. history.

To my knowledge, the USDA has not asserted that there is any evidence of contaminated food or any evidence of any illness. I am not aware that there has ever been—that there has ever before been a meat recall of this magnitude where there was no evidence of contaminated food and no evidence of any illness. Our company

is ruined. We cannot continue. Approximately 220 employees have lost their jobs. The financial impact affects just not our company but many others. Because our company supplies beef that is commingled with other products and put into commerce, the financial impact of the two employee's actions and the recall is devastating. The conduct appearing in the video that I saw is sickening. That is not the company I know.

I agree with everyone who is shocked and horrified at the video. I know that this committee was upset I did not appear before you earlier in response to the invitation sent a few weeks ago. I sincerely apologize for that. It had been a chaotic time for me, my company, and my family. I know that this committee deserves the respect of witnesses, and I appreciate the opportunity to speak today.

[The prepared statement of Mr. Mendell follows:]

WRITTEN STATEMENT OF STEVE MENDELL

My name is Steve Mendell. I am the President of the Westland / Hallmark Meat Co. The company is in the business of harvesting and processing beef under the Federal Meat Inspection Act. Until a few weeks ago, my company was viewed as having an excellent record in the areas of humane handling and food safety. We took pride in this record.

In early-February, I was contacted by a Washington Post reporter. The reporter sent me an excerpt of a video taken by the Humane Society. I was shocked. I was horrified. I was sickened. I agree that the actions shown in the video were inhumane and are completely reprehensible. The actions were in blatant violation of company policies and procedures. These policies and procedures were not just documents but were implemented through training and regular compliance audits. The company has always been committed to best practices when it comes to humane handling and food safety.

In 2007, the company passed seventeen outside audits and twelve additional internal audits. The company has been regularly audited by the Audit, Review and Compliance Branch of the USDA. The company also has been regularly audited by Silliker Inc., as well as other independent third-party auditors. The audits were comprehensive. I have attached a few of the more recent audit reports. They are: the November 16, 2007 HACCP Consulting Group Audit Report; the November 21, 2007 Silliker Animal Welfare Audit Report; and the February 1, 2008 V.E. Coiner Independent Review. I ask that these reports be made part of this record. The company received the highest scores in the areas of humane handling of cattle and food safety. The company also requires that all employees undergo extensive training and monthly retraining to ensure compliance with company policies and procedures.

From the video I saw, two employees blatantly violated those policies and procedures. It appears that non-ambulatory cows, known as "downer cows," were pushed with a forklift, were

shocked with an electrical prodder, and had water hoses sprayed in their nose in an effort to get the cows on their feet. As soon as I saw the video, the employees were immediately terminated. Our company has a "zero tolerance" policy for inhumane treatment. The video was apparently taken in October or November 2007. Had I known about the employees' actions sooner, I would have terminated the employees on the spot.

I want to emphasize though that the activities shown on the video are not a "food safety issue." The cows shown in the video could not walk, were designated to be euthanized and were not put into commerce. These cows would not have passed USDA inspection to enter the processing line. To put it in practical terms, these cows would not have been physically able to walk up the 90 foot single-file chute that leads to the "knock box" where the processing begins. Instead, these cows appear to have been among the 10 – 15 each day that are euthanized outside the plants in trailers and the pens and that are removed from production because they are non-ambulatory. While these cows should be treated humanely and they were not, these cows were not harvested and they did not enter the food system. They were not slaughtered, ground or sold. They were euthanized and removed.

I also want to emphasize that it would be financial suicide for a company to harvest or process a cow that it believes to be sick. The company does not pay suppliers for the cost of a cow deemed unfit for human consumption and there is therefore no financial incentive to bypass the regulations. A single sick cow that enters production also has the capacity to ruin an entire day's worth of production. It is for this reason that the company would have no interest in processing a non-ambulatory cow. It is also for this reason that the company strictly complied with post-mortem inspection and quality assurance requirements. After a cow passes the USDA ante-mortem inspection, physically walks up the 90 foot single-file chute and then enters the "knock box," where the cow is euthanized, the spinal cord and other specified risk material

associated with BSC is carefully removed from the cow. Major organs are also removed and carefully inspected and tested for any sign of illness or disease. The carcass is examined at several quality control stations and then by the USDA inspector. As a result of this post-mortem inspection process, approximately 20 – 30 cows are removed from production each day.

In audit after audit, the USDA, other outside auditors, and our internal audits found negative test results for the presence of E. coli and Salmonella. The audits also reported that the company was complying with humane handling laws and company policies. In February, my management and I examined what steps we could take to ensure that no inhumane handling occurred. We reviewed our policies which are in accordance with the guidelines of Dr. Temple Grandin, a world-renowned expert in humane handling practices. We confirmed that the two fired employees, as well as the Humane Society employee, had participated in extensive training and retraining. We hired Dr. Erica Voogood to ensure that we had best practices. We hired all new employees for our pen areas and a new pen manager. We installed seventeen cameras that would videotape the unloading, pen and chute areas so we could monitor compliance with humane handling practices. We hired a company called Arrowsight Security to review the videotape twenty-four hours a day and seven days a week. Dr. Grandin and Dr. Voogood were also going to review random excerpts of the video once a week.

We were taking all of the steps we could to ensure for USDA, our customers and the public that the inhumane handling shown in the video would never recur. I then received a call from the USDA indicating that a second video had been received – a video which I asked to see, which was not provided and which I have never seen. At the urging of the USDA, however, our company voluntarily recalled all products containing any trace amounts of beef harvested by our company for the last two years. Our company is now the subject of the largest meat recall in U.S. history. To my knowledge, the USDA has not asserted that there is any evidence of

contaminated food or any evidence of any illness. I am not aware that there has ever before been a meat recall of this magnitude where there is no evidence of contaminated food and no evidence of any illness.

Our company is ruined. We cannot continue. Approximately two hundred and twenty company employees have lost or are about to lose their jobs. The financial impact affects just not our company but many others. Because our company supplies beef that is commingled with other meats and put into commerce, the financial impact of the two employee's actions and the recall is devastating. For instance, our company sold approximately $80,000 of beef to a customer. Because that beef was commingled in the customer's products, that customer has suffered millions of dollars of damages. Hundreds of thousands of pounds of meat have been destroyed. I cannot estimate the total amount of financial loss, except to say that it is in the hundreds of millions of dollars.

The conduct appearing in the one video I saw is sickening. That is not the company I know. I agree with everyone who is shocked and horrified by the video. At the workplace and at home, I have received dozens of calls not just from reporters but from persons yelling, screaming, making death threats, and saying that they are praying for us to suffer and die like the cows. My employees have suffered emotionally. My family has suffered. I know that this Committee was upset that I did not appear before you earlier in response to the invitation sent a few weeks ago. I sincerely apologize. It has been a chaotic time for me, my company and my family. I know that this Committee deserves the respect of witnesses. I appreciate the opportunity to speak with you today.

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November 16, 2007

Conducted By:
John Miller
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REVIEW SUMMARY

On November 13 and 14, 2007 an on-site assessment was performed at Westland/Hallmark Foods, LLC, hereafter WHMC, Federal Establishment 336, located at 13677 Yorba Avenue, Chino, California by the HACCP Consulting Group (HCG), L.L.C. The review was performed at the request of Westland/Hallmark Foods Management. The focus of the review was to ensure that Establishment 336 continues to be in compliance with the regulatory requirements of Code of Federal Regulations 9, specifically parts 310.22, 313, 416 and 417 as well as the company's written programs. The results of the review are as follows:

OVERVIEW

Westland/Hallmark slaughters and fabricates approximately 500 beef animals per day on one production shift. The beef cattle that are slaughtered and fabricated are from domestic stock only and the company maintains documentation to support the origin of the animals. The company is an approved supplier to the Federal School Lunch Program. As such the company is subject to ongoing audits by AMS. WHMC has in place a well developed Quality Management System that includes Training Programs for employees, Prerequisite programs to support the Food Safety System through ongoing internal company audits, and procedures for monitoring the systems that are in place. Management uses the monitoring results to track and identify trends in the facility that may impact upon the safety and quality of the products.

HUMANE HANDLING PROCEDURES

WHMC has a well designed Humane Handling Program in place to ensure that live animals that are received for slaughter and fabrication are treated in a manner conducive to the tenets of established humane handling practices. The program is designed using guidelines developed by Dr. Temple Grandin of Colorado State University. Live animal haulers that bring cattle to the facility are required to read WHMC rules for unloading animals. Their understanding of the requirements is documented by the company. In addition, all plant employees that work with live animals are provided with training in Humane Handling practices. During a review of the live animal unloading and holding pen practices, the animals were unloaded properly with a minimum amount of stress, placed in holding pens that were clean, and provided with sufficient water. There was no evidence of crowding and minimal vocalizing by the cattle. The pens, including fencing, appeared to be in good repair. The company inspects the pens on a daily basis to ensure that the enclosures remain in good repair and do not have any obstructions or other deficiencies that could cause harm to the animals. The results of the review are documented.

WHMC has a written procedure for ongoing maintenance of the stun guns. Each stun gun is identified, inspected daily, and replaced if they are not operating properly. The personnel performing stunning of cattle are trained and monitored during slaughter operations. Results of the monitoring are recorded.

SPECIFIED RISK MATERIALS

All animals slaughtered and fabricated by WHMC are considered to be thirty months of age or more. As such all parts of the animal that are considered to be SRMs are removed during processing and disposed of. The company has an intensive written procedure for removal and handling of these materials. The lone exception to the procedure is one consignee that receives beef arm chucks under seal from WHMC and bones them under their own in house procedures. A "Chain of Custody" is maintained for these products during transfer from WHMC to the consignee.

All products that are fabricated in the plant are beef that is slaughtered in the facility with the exception of Beef Plates that are purchased from an outside domestic source. That product is fabricated on a dedicated line, identified throughout the processing and packaging, and is not commingled with any other product in the plant. WHMC fabricates product in the boning department in lots of 60 carcasses. The product from each lot is provided with a separate identity throughout processing, packaging, and shipment. In addition, there is a physical time break in the process between lots to preclude any possibility of commingling product from different lots. This allows WHMC to maintain positive product identity if the need should arise.

MICROBIOLOGICAL TESTING

Each Combo of Beef Trim is tested at the end of the Fabrication process using N=60 method of sample collection. The product is sampled for TPC, *coliforms, Listeria spp., Salmonella, and Escherichia coli O157:H7.* The company testing results that were reviewed were all negative for E. coli and extremely low for non pathogenic organisms.

In addition, WHMC has an environmental testing program in place. The various areas of the facility are mapped and color coded for sampling purposes. The results are recorded and graphed on computer for tracking of any positive results. Employee hand tools, garments, and food contact surface equipment is sampled both during pre-operational inspection and during operations. All of the company results that were reviewed showed that the sanitation program is extremely effective. The fabrication department contact surfaces are scrapped and sanitized at mid shift break and showed very low microbiological organism levels.

The company samples one carcass for each 300 animals slaughtered for generic E. coli, Biotype 1 to comply with 9 Code of Federal Regulations (CFR) part 310.25. The sample results have been very good.

SANITATION STANDARD OPERATING PROCEDURES (SSOP)

Slaughter Preoperational Walk Thru

During a pre-op walk thru, the reviewer observed plant employees inspecting equipment and setting up various equipment. The facilities and equipment were clean and employees appeared to have a thorough understanding of sanitation requirements. No deficiencies were observed.

Fabrication SSOP Pre-Operational Walk Thru

Plant employees charged with performing the pre-op inspection in the fabrication department were using proper techniques when inspecting the equipment. Although they were already conducting the inspection and setting up the department for processing, the contact surfaces and surrounding areas of the department appeared to be clean. The employees were using proper handling techniques from a sanitary standpoint when placing product totes and other hand equipment in their respective areas.

HACCP SYSTEM

The HACCP plans are well designed, thorough, and reflect the processes in the plant's operation. The process steps in the flow charts accurately depict the steps in the Hazard Analyses. The Hazard analyses reflect well thought out reasoning and address product flow in the respective operations as they are identified on the flow charts. In addition the plans reflect a well grounded and thorough working knowledge of the principles of HACCP by the plant's food safety team.

WHMC has two validated Critical Control Points (CCP) in the HACCP system. The first CCP is application of Lactic Acid. The acid is applied via a cabinet system at solution strength of up to 5 percent. The other design parameters are a solution temperature of 140 degrees Fahrenheit and pressure of 40 pounds per square inch.

The second CCP is Zero Tolerance. A trained company Quality Control Employee selects 3 carcass sides each hour during production and examines them for identifiable contaminants, fecal, ingesta, or milk.

In addition, lactic acid is also applied to cheek, head and weasand meat and other variety meat items that are harvested during the slaughter process.

WHMC's HACCP plan includes a temperature CCP of carcass surface (44.6 F) in the holding cooler and the fabrication process.

The company employees other processing aids to help ensure the safety of the food products. They utilize three steam vacuum stations in the slaughter process as well as a hot water rinse cabinet that sprays hot water at a temperature of 195 degrees Fahrenheit on each carcass for 12 seconds. One of the three steam vacuums is located at pre-evisceration followed by a pre-evisceration lactic acid spray. Although studies have shown that this helps to reduce bacteria on carcass surfaces, it is not a validated intervention in the HACCP plan. During observation of the slaughter process, the reviewer noted that the person operating the steam vacuum on the lower carcass surfaces was not completely vacuum the lower neck area and front shank areas of the carcasses. Plant management immediately reacted to the observation and instructed the plant employee on proper vacuum techniques.

As a further aid, the company applies Inspexx to each carcass side during carcass breaking process. The acid is applied at a solution rate of two hundred parts per million to the entire surface of each carcass. During the review, the employee applying the inspexx was not applying the material to the upper hock area of every carcass. Plant management immediately provided instruction to the person performing the process

To further emphasize good manufacturing practices or Best Practices, WHMC has an extensive training program for all employees in the facility. Employees working in the slaughter process are trained in animal handling techniques such as proper sterilization of hand tools, including use of a two knife system when making various cuts in the process as well as effective routine cleaning of hands and garments to preclude cross contamination of carcasses.

CONCLUSIONS:

Based on observations gleaned during the review, it is evident that Westland/Hallmark Meat Company has a sound food safety system that goes well above and beyond that which would normally be expected or required from a regulatory standpoint. The company management is rightfully proud of their food safety system and willingly shared information and their internal programs with the HCG.

If you have any questions, please feel free to contact me at: 916-996-0285

Sincerely,

John H. Miller VP
HACCP Consulting Group, L.L.C.
9346 Winding River Way
Elk Grove, California 95624

Attachment:
Attached is a list of the programs associated with the plant's Quality Management System (QMS)

QUALITY MANAGEMENT SYSTEM

CONTINUOUS IMPROVEMENT OBJECTIVES

A Quality Management System (QMS) has been developed to ensure that the high quality products that are produced and supported by their HACCP, SSOP's , Prerequisite Programs and GMP's are consistently achieved, by evaluating each program and their supporting sub-categories as a cohesive and supporting unit. WHMC has been able to monitor and improve their general operations by ongoing and documented planned improvements.

WHMC is able to prepare, execute and augment their operations by reviewing monthly internal GMP audit reports, pre-operational, operational and maintenance logs. In-house audits are used as a pro-active tool to monitor, correct and assign improvements to noted deficiencies/deviations as well as plant operations, programs, employee practices and the physical condition of the facility. Committee members review pertinent collective documents which results with planning, creating and implementing documented corrective actions including applicable preventive measures in order to prevent reoccurrences.

A quorum has been established and applied to the QMS members for individual responsibility and accountability in order to ensure that total and consistent conformity is met. Copies of each audit, including noted

deviations, planned corrective actions, and completed corrective actions are forwarded to pertinent Department Personnel as well as upper management. All generated audits are filed in chronological order for any needed future references.

The entire facility is reviewed on a monthly basis or sooner if needed. Plant audits involve facility walkthroughs, reviewing specific areas such as; the integrity of the each buildings infrastructure with regards to sanitation, applicable daily QC documents, equipment maintenance, humane handling and worker practices.

Reviews by committee members of past documented audits, including pertinent pre-operational and operational deficiencies, and Non-compliance records cited by the USDA are conducted. In addition Committee Members collectively and accurately measure deviations that were corrected at set time tables as well as the most recent deviations that were noted during each post audit. All corrected areas are individually reviewed and verified in a series of planned documented plant meetings.

The monitoring of their food safety systems is of the utmost importance. QC personnel who are assigned to monitor, record and review records are trained on an annual basis or sooner if needed. This training includes the following categories:

- **Basics of HACCP, SSOP, GMP's & Pre-requisite Programs**
- **Monitoring of CCPs as prescribed by the HACCP System, (Including scientifically established critical limits);**
- **Corrective Action(s) procedures in the event that critical limits have not been met.(Which includes corrective action plan(s), (Form 417.3 FSIS/USDA)**
- **Procedures and records of calibration;**
- **HACCP documents are consistently signed and dated;**
- **Verification of HACCP, SSOP & Prerequisite Systems which is kept for a minimum of one (1) year;**
- **Pre-operational Sanitation Checklist;**
- **Daily Pre-operational Sanitation Deficiency Report;**
- **Operational Sanitation Checklist;**
- **Daily Operational Sanitation Deficiency Report;**
- **Hooks For Laborers;**

- **Personal Hygiene Log;**
- **Temperature Checklist of Sterilizers;**
- **Lactic Acid Soultion Monitoring Report;**
- **Inspexx 200 Solution Monitoring Report;**
- **Quad DS Solution Monitoring Report;**
- **Quad DS Solution Mix – Hand Held Sprayers – Monitoring Form;**
- **Inspexx 200 Solution Mix – Hand Held Sprayers – Monitoring Form;**
- **Quad DS Floor Sprayer Report;**
- **Daily Calibration Check & Verification;**
- **Production Report for Harvesting, (Zero Tolerance, Lactic Acid Intervention, Product Temperature Stage)**
- **Production Report For Raw Not Ground Meat Products (Product Temperature Stage Monitoring);**
- **Production Report For Raw Not Ground Beef Products, (HACCP);**
- **Mid-Shift Wet Clean-Up;**
- **Meat CO2 Injector Monitoring Checklist;**
- **Storage Cooler Ambient Temperature Monitoring;**
- **De-boning Cooler Ambient Temperature Monitoring;**
- **Monitoring of SRM's;**
- **Government/Commercial On-Line Inspection of Boneless Beef;**
- **Daily Pre-Shipment Sanitation Cargo Bay Inspection;**

The areas that are evaluated by Committee members are;

- **HACCP, (Awareness concerning revisions, etc.)**
- **SSOP's, (Awareness concerning revisions, etc.)**
- **Pre-Requisite Program**
- **GMPs, (Pest Control, Employee Practices)**
- **Plant Defense Program**
- **Exterior Audit Results (Dry storage & VersaCold exterior freezer)**
- **Microbiological Training/Test results/Evaluations, (In-house & Out-house)**
- **Recall Exercises**
- **Product Integrity Control/Continual Improvement**
- **Return Product Control**
- **Cold Chain Management of Storage Product Control**
- **Dry Storage Control, (Including Material Rotations, Guarantee's, etc.)**
- **BSE Control Points**
- **Animal Welfare Controls**

- **New Employee Orientation & Human Resources, (Job Safety Analysis & Descriptions)**
- **Plant Sanitation Reviews/Correspondence/Hazardous Communication/Working with Chemicals Training**
- **Business Emergency Contingency Plan**
- **Preventive Maintenance, (Including Protocols for Trucks & Trailers, Trailer Failure, New Equipment, General Construction)**
- **Facilities and Practices, (Storage coolers, fabrication, grinding, harvest floor)**
- **Pest Control Evaluation with Orkin**
- **Customer Complaints**
- **Employee Practices/Training, (harvest, fabrication & grinding)**
- **Exterior areas, (Trash, Cardboard)**

QMSC COMMITTEE MEMBERS

- Stan Mendell, WMC, Plant Manager
- Pablo Salas, HMC, Plant Manager, Harvest
- Tony Cuevas, WMC Quality Assurance, De-boning
- Gustavo Manzo, HMC, Supervisor, Harvest
- Martin Laguna, Quality Assurance, Harvest
- Henry Wong, Grinding Manager
- Martin Gonzalez, Quality Assurance, Grinding
- Tony Gonzalez, Shipping & Receiving Supervisor
- Tony Padilla, Plant Maintenance Lead Supervisor
- Steve Sayer, Principle

In the event of a 3rd party audit the QMSC would meet to evaluate plant conditions and practices. Noted deviations will be documented with a planned corrective action list created. Specific assigned roles to procure applicable documents involve:

- Harvest CCP's
- De-boning CCP's
- Grinding CCP's
- HACCP Program
- SSOP Program
- GMP Programs
- Prerequisite Program
- Animal Welfare Program

- Microbiological Analysis
- Regulatory Directives and Notices
- Non-Compliance Records

Assignment for corrections would be developed and assigned to all applicable documentation listed above. Revised procedures will be noted for accuracy and compliance since the last documented audit. Final audit results were used for among other areas, Employee Training, Planned Improvement Program, Continuous Improvement, Employee Safety Committee, and USDA Weekly Exit Meetings

SILLIKER
Food Safety & Quality Solutions

AUDIT REPORT

Animal Welfare Audit
BEEF*

for:

Westland Meat Co/Hallmark Meat Packing: Chino, CA

Report Date
November 21, 2007

Audit by
Stacy Riggs

Silliker, Inc.

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*Criteria for this audit are based on "Recommended Animal Handling Guidelines and audit Guide, 2007 edition" published by the American Meat Institute Foundation.

ANIMAL WELFARE AUDIT: BEEF

Company Name: Parent Company:	Westland Meat Company/Hallmark Packing Company	**Audit Date:** **Start & End Time:**	November 21, 2007 8:00am - 12:00pm
Plant Address:	13677 Yorba Avenue Chino, CA 91710	**Silliker Auditor:**	Stacy Riggs 903-243-3101
Primary Contact:	Steve Sayer	**Telephone:**	909-590-3340
Email:	steve_sayer_westland@yahoo.c	**Fax:**	909-590-3320
USDA est #:	336	**Line Speed:**	50 head/hour
Pass/Fail:	Pass	**Was religious slaughter performed during the audit?**	**No**
		Was conventional slaughter performed during the audit?	**Yes**

AUDIT SUMMARY - ANIMAL SURVEY

AMI Core Criteria	Passing Score	Score
Electric Prodding	25% or less prodded	6 %
Vocalization	3% or less (conventional) 5% or less (ritual or with use of head holder)	0%
Slips and Falls	Truck unload - 1% or less falls 3% or less slips In plant - 1% or less falls 3% or less slips	0% 0% 0% 0%
Stunning Accuracy	95% or greater accuracy	97.8%
Bleed Rail Insensibility	100% Insensible	0%
Access to water	Yes, water provided	Yes
Willful acts of Abuse	No willful acts of abuse	No

Auditor Signature: Stacy Riggs

Stacy Riggs 903-243-3101; stacy.riggs@silliker.com

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

AUDIT SUMMARY

Category	Possible Points	Actual Points	Percentage
I. Livestock Receiving	25	25	100
II. Livestock Condition	10	10	100
III. Handling and Holding	45	45	100
IIII. Observations	30	26	86.7
Total	110	106	96.4

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

Summary of Audit Findings
Critical / Major Areas (Questions scoring a 1 or 2):

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

5

1.0	A. Livestock Receiving	Rating
1.	Company provides written expectations for humane handling to transporters. Guidelines must be posted or delivered to transporters. (1 element)	5
2.	Trailer should be cleaned regularly to prevent heavy accumulation of feces. Manure should not surpass hooves. Trailers must have slip resistant floors and no potential injury points (broken glass, sharp metal edges, etc.) (3 elements)	5
3.	Ramps and unloading area should be slip resistant with no accumulated manure or standing water. There are no potential injury points (broken gates, sharp metal edges, etc.) in unloading areas. (3 elements)	5
4.	The plant should discourage use of electric prods during unloading of animals. Less than 5% of animals should be electrically prodded. (1 element)	5
5.	Animals that have become non-ambulatory in transport are handled humanely and per company's established procedures. Auditor verifies that procedures require stunning of animal prior to being physically removing from trailer or transport vehicle. (Reason for this verification is it is very unlikely auditor will be able to visually verify an animal being stunned on a transport vehicle.) (2 elements)	5

Possible Points **25**

Actual Points **25**

Comments

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

2.0	A. Livestock Condition	Rating
1.	Facility has an established procedure for animals that become non-ambulatory after ante-mortem inspection. Procedure includes stunning animal prior to dragging it from pens, chutes, or ramps. (2 elements)	5
2.	Any dead-on-arrivals (DOAs) carcasses should be staged out of public view. The facility must keep track of DOAs. (2 elements)	5

Possible Points **10**

Actual Points **10**

Comments

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

3.0	A. Handling and Holding	Rating
1.	All pens should have slip resistant floors and be cleaned or bedded daily. Manure should not surpass the hoof of the animal, and standing water should not be present. Crowd pen, chutes, restrainer, and knock box areas have slip resistant floors. (Verify maintenance records are being maintained.) (5 elements)	5
2.	Pens, chutes, restrainer area, and knock box should be in good repair with no potential injury points (broken gates, sharp metal edges, broken concrete, etc.) present. There are no potential distractions present or observed in the pens, chutes, restrainer, or knock box area. Distractions could include poor design, poor lighting/shadows, out of place objects, voices/noise, debris, etc. Solid sides should be present on crowd pen and chute sides to prevent distractions. (3 elements)	5
3.	There is a preventative maintenance program in place for the stunning equipment. There must be back-up stunning equipment in the stunning area. Stunning equipment must also be available to the receiving area for downers on trailers and in pens. (3 elements)	5
4.	Plant must have an Emergency Livestock Management Plan. The plan should address potential risks and actions for insuring animal welfare, based on geographic location and climate. The plan should be reviewed at least annually. (3 elements)	5
5.	Holding pens must not be overstocked. Animals should have ease of mobility. Crowd pen should be stocked less than 3/4 full. Crowd pen gate should not be used to push animals. (3 elements)	5
6.	All holding pens must have unrestricted access to potable water. Troughs should be regularly cleaned and water cannot be frozen. Animals must have access to feed if held for over 24 hours. (2 elements)	5
7.	The company's training program must reflect procedures and policies for receiving livestock, condition of livestock, holding and handling, and stunning. Retraining should be done at least annually. Records of training must be maintained. (3 Elements)	5
8.	Company performs animal welfare self-audits at least weekly. Records of the self-audits are maintained. Consistent deviations or observations must have corrective actions completed with timelines. The observations of insensibility, stunning accuracy, electric prod usage, vocalization, and slips and falls must be included in the self-audits conducted. (3 elements)	5
9.	**ANY WILLFUL ACT OF ABUSE IS GROUNDS FOR AUTOMATIC AUDIT FAILURE. 1) DRAGGING A CONSCIOUS, NON- AMBULATORY ANIMAL; 2) PURPOSEFUL SLAMMING OF GATES OF LIVESTOCK; 3) PURPOSEFUL DRIVING OF LIVESTOCK ON TOP OF ONE ANOTHER; 4) HITTING OR BEATING AN ANIMAL. (1 element)**	5

Possible Points	**45**
Actual Points	**45**

Comments

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

4.0	A. Observations	Rating
1.	SLIPS AND FALLS- UNLOADING: DETERMINE THE NUMBER OF SLIPS AND FALLS DURING UNLOADING AND RECORD PROBABLE CAUSES if any are observed. Count the number of cattle that slip or fall during unloading. In large plants unloading should be continuously observed until 100 animals from three different vehicles are scored. An equal number of animals from each deck should be scored. Vehicles should be scored in the order of arrival at the unloading ramp. In small plants where vehicles are not continuously unloaded, a single vehicle should be scored. If no vehicle arrives, the score sheet is marked unloading not observed. A SLIP IS RECORDED WHEN A PORTION OF THE LEG, OTHER THAN THE FOOT TOUCHES THE GROUND, OR A FOOT LOSES CONTACT WITH THE GROUND IN A NON- WALKING MANNER. A FALL IS RECORDED WHEN AN ANIMAL LOSES AN UPRIGHT POSITION SUDDENLY AND A PART OF THE BODY OTHER THAN THE LIMBS TOUCHES THE GROUND. EXCELLENT = NO SLIPS OR FALLS = 5; ACCEPTABLE = 3% OR LESS SLIPPING OR 1% OR LESS FALLS = 3; NOT ACCEPTABLE = GREATER THAN 1% FALLS OR GREATER THAN 3% SLIPS= 1	5
2.	SLIPS AND FALLS- STUNNING CHUTE AREAS: DETERMINE THE NUMBER OF SLIPS AND FALLS DURING HANDLING IN ANY OF THE FOLLOWING LOCATIONS: CROWD PEN, SINGLE FILE CHUTE, BARNS, ALLEYS OR STUNNING BOX. Score a minimum of 50 animals in large plants. A SLIP IS RECORDED WHEN A KNEE OR HOCK TOUCHES THE FLOOR. IN CATTLE STUN BOXES AND THE SINGLE FILE CHUTE, A SLIP SHOULD BE RECORDED IF THE ANIMAL BECOMES AGITATED DUE TO MULTIPLE SHORT SLIPS. A FALL IS RECORDED IF THE BODY TOUCHES THE FLOOR. EXCELLENT = NO SLIPS OR FALLS = 5; ACCEPTABLE = 3% OR LESS SLIPPING OR 1% OR LESS FALLS = 3 ; NOT ACCEPTABLE = GREATER THAN 1% FALLS OR GREATER THAN 3% SLIPS= 1	5
3.	USE OF ELECTRIC PRODS FROM CROWD PEN TO RESTRAINER / KNOCK BOX: MONITOR THE PERCENTAGE OF 100 CATTLE PRODDED WITH AN ELECTRIC PROD AT THE RESTRAINER ENTRANCE. Facilities with two or more single file chutes should be audited, so there is an even distribution of animals observed among all of the single file chutes. If multiple employees are using prods, score 100 animals passing by each employee. Add the percentages together to determine the final score. Note whether or not a prod was used for each animal and the apparent reason for prod use in the comments. ELECTRIC PRODS SHOULD ONLY BE USED WHEN NECESSARY. ELECTRIC PRODS AND ANY OTHER OBJECTS SHALL NOT BE USED ON SENSITIVE AREAS (FACE, ANUS AND GENITAL). ELECTRIC PRODS SHOULD NOT BE USED IN HOLDING AREA OR CROWD PEN. EXCELLENT = 5% OR LESS PRODDED = 5; ACCEPTABLE = 25% OR LESS PRODDED = 3; NOT ACCEPTABLE = GREATER THAN 25% PRODDED = 1	3
4.	VOCALIZATION: MONITOR THE NUMBER OF CATTLE THAT VOCALIZE (PROVOKED BY STRESS OR AGITATION) IN THE CROWD PEN, LEAD- UP CHUTE STUNNING BOX OR RESTRAINER. SCORE A MINIMUM OF 100 ANIMALS IN LARGE PLANTS AND 50 OR AT LEAST ONE HOUR OFPRODUCTION IN SMALLER PLANTS. VOCALIZING ANIMALS IN THE CROWD PEN AND LEAD- UP CHUTE ARE SCORED DURING ACTIVE HANDLING. SCORE AN ANIMAL AS A VOCALIZER, IF IT MAKES ANY AUDIBLE VOCALIZATION. Determine cause for animals that are vocalizing and include in comments. AMI GUIDELINES DEFINE ACCEPTABLE VOCALIZATION AS UP TO 3% FOR CONVENTIONAL SLAUGHTER AND UP TO 5% IN KOSHER OR HALAL OPERATIONS OR ANY OPERATION USING A HEAD HOLDER. EXCELLENT = LESS THAN 1% VOCALIZATION = 5; ACCEPTABLE = 3% or less (conventional) or 5% or less (ritual or with use of head holder) VOCALIZATION = 3; NOT ACCEPTABLE = GREATER THAN 3% (CONVENTIONAL) OR 5% VOCALIZATION (RITUAL OF WITH USE OF A HEAD HOLDER = 1	5
		Possible Points

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

A. Observations

5.	**STUNNING ACCURACY (CONVENTIONAL ONLY): PLANNED DOUBLE KNOCKING IS PROHIBITED. IF A NON- PENETRATING CAPTIVE BOLT IS USED, THE ANIMALS SHOULD BE BLED PROMPTLY BUT NO LONGER THAN 60 SECONDS AFTER STUNNING TO AVOID RETURN TO SENSIBILITY. THE FIRST SHOT MUST RENDER THE ANIMAL INSENSIBLE. SCORE 100 CATTLE IN PLANTS WITH LINE SPEEDS GREATER THAN 100 CATTLE PER HOUR. FIFTY CATTLE OR AT LEAST ONE HOUR OF PRODUCTION SHOULD BE AUDITED IN SLOWER PLANTS PROCESSING FEWER THAN 100 HEAD PER HOUR. RECORD PERCENTAGE OF ANIMALS THAT WERE STUNNED TWICE AND PROBABLE CAUSES AND INCLUDE IN COMMENTS. Auditor is to list stunning method used in comments. EXCELLENT = 99- 100% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 5; ACCEPTABLE = 95-98% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 3; NOT ACCEPTABLE = LESS THAN 95% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 1**	3
6.	**BLEED RAIL INSENSIBILITY SURVEY: ANY SENSIBLE ANIMAL ON THE BLEED RAIL CONSTITUTES AN AUTOMATIC AUDIT FAILURE. SCORE A MINIMUN OF 100 ANIMALS IN LARGE PLANTS. FIFTY CATTLE OR AT LEAST ONE HOUR OF PRODUCTION SHOULD BE AUDITED IN SLOWER PLANTS PROCESSING FEWER THEN 100 HEADS PER HOUR. IT IS CRITICAL THAT ANIMALS SHOWING SIGNS OF A RETURN TO SENSIBILITY BE RESTUNNED IMMEDIATELY. THERE IS ZERO TOLERANCE FOR BEGINNING ANY PROCEDURES LIKE SKINNING THE HEAD OR LEG REMOVAL ON ANY ANIMAL THAT SHOWS SIGNS OF A RETURN TO SENSIBILITY; however, it is important to complete the audit and note observations about insensibility. Insensibility is characterized by a floppy head, straight tongue hanging out, no righting reflex, eyes are in a blank stare (no eye tracking), no natural blinks occurring. EXCELLENT =100% INSENSIBLE = 5; NOT ACCEPTABLE = LESS THAN 100% INSENSIBLE = 1**	5

30

26

Comments

3. Observed three head out of the 50 head observed, prodded, while being moved from the crowd pens to the knock box. Use of electric pod = 6 %

5. Observed one head (#7) double-knocked, out of the 45 head observed knocked during a one hour period. Stunning accuracy = 97.8 %

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

February 1, 2008

To: Steve Mendell, President
Westland/Hallmark Meat Company
13677 Yorba Avenue
Chino, CA 91710

From: V E Coiner DVM
Meat Consultant

Thank you for asking me to visit your official establishment and provide you with my independent review.

I retired from supervisory positions in USDA's Food Safety and Inspection Service in 1997. I worked for FSIS for 26 years in many parts of the U.S., starting as a Vet Medical Officer at a slaughter plant. Since retirement, I advise and counsel meat firms and provide my independent views based on my substantial experience.

Steve, I have reviewed the records and programs you have at your plant; which Steve Sayer has in place at your plant and these are the best I have ever seen in any plant.

You have excellent records of all of your training programs and ongoing training of all employees.

Your plant has passed numerous audits on humane handling of animals in this plant in the year of 2007 and has no failures; which you should to be very proud of.

You have no failures of E-coli and Salmonella samples: which again shows you have an excellent control over all the harvesting and processing in this plant.

I have also gone through the AM pens and slaughter floor and I see a few windows of opportunities or enhancements, which as we discussed should be initiated at your plant.

(1) You need to hire an employee to monitor the handling of all the livestock full-time.
(2) You should eliminate all weak animals from entering your plant premises. I have talked to Donnie Hallmark. You need to make the dairymen and cattle buyers aware of this.
(3) You also, need to place a hasp and FSIS seal on the old downer door as a further enhancement to prevent any possible way of allowing a weak animal to enter the slaughter floor.

Again, I would like to commend you and all of your employees for the fine job they have been doing at this plant to produce an excellent product for consumer.

If I can be of any assistance to you in the future please call me anytime at 208-373-0669 or 208-863-3399.

Mr. STUPAK. Thank you, Mr. Mendell. You have two reports you wanted to put in, and I objected. I just want to clarify a couple things. On the first report, the audit report from Silliker, the concern I have is the report dated November 21, 2007, the small print, fourth paragraph says the name of Silliker or its affiliates or any of its employees may not be used in conjunction with any marketing or promotion or in any publication concerning or relating to the client or its products and services without the prior written consent of Silliker. Do you have the prior written consent of Silliker to submit this?

Mr. MENDELL. I don't.

Mr. STUPAK. OK.

Mr. SHIMKUS. Mr. Chairman, could you yield on that for a second, and maybe counsel can help us too on both sides. It is my understanding that you actually own this report. You paid for it. So I am not sure that application would apply to your ability to—it is a service rendered. It is not marketing. It is not——

Mr. HUTCHINSON. Mr. Chairman, if I might, the disclaimer on the front says the report is furnished solely for the benefit of the above-named client in connection with the auditing services so it would be our view that this was an audit in the regular course of business that we paid for and it would be relevant to the committee's consideration when appropriate.

Mr. STUPAK. OK. So upon your advice you are having your client then submit this report?

Mr. HUTCHINSON. Yes.

Mr. STUPAK. Despite the disclaimer, we don't have written notification? OK. I am just trying to protect the integrity of everybody here. OK. And then on the—I guess the other one doesn't have that disclaimer, just some general—would you take same advice that your client paid for it, it is his report, therefore, it would be appropriate to submit it for the record, Mr. Hutchinson?

Mr. HUTCHINSON. Which one are you referring to?

Mr. STUPAK. The one dated, let me get the exact date, HACCP Consulting Group from Fairfax, Virginia, November 16, 2007.

Mr. HUTCHINSON. Correct.

Mr. STUPAK. So these are 5 days apart, these two reports, and you would like them both submitted for the record.

Mr. MENDELL. Yes, indeed.

Mr. STUPAK. OK. Without objection. Hearing no objections they are part of the record.

Mr. HUTCHINSON. There is one more letter that was attached to that package, a letter of February 1, 2008. Do you have that?

Mr. STUPAK. Yes, I do.

Mr. HUTCHINSON. We would ask that to be made a part of the record as well.

Mr. STUPAK. This is the letter from Dr. Coiner, Meat Consultant? He is a Doctor of Veterinary Medicine, is that correct?

Mr. MENDELL. Yes, that is correct.

Mr. STUPAK. That is the one? OK. It is dated February 1, 2008.

Mr. MENDELL. That is correct.

Mr. STUPAK. That is after these incidents. I didn't know if you——

Mr. MENDELL. That is correct. That is after.

Mr. STUPAK. But you still want it?

Mr. MENDELL. Yes.

Mr. STUPAK. Without objection, February 1, 2008, letter from V.E. Coiner, Doctor of Veterinary Medicine, Meat Consultant, will be part of the statement.

Mr. HUTCHINSON. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you. Let us begin questioning then. Mr. Mendell, you state your company according to what I have seen and read, the company began, at least you, in 1990 near Los Angeles, correct?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. And then you bought this slaughterhouse later?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. OK. Were you aware then in 1990 that the Humane Society in neighboring Panoma found recurring problems of the plant handling cows?

Mr. MENDELL. No, sir.

Mr. STUPAK. OK. Are you aware that in 1993 part of the Jack-in-the-Box where we had the E. coli and people were injured, your company settled part of that claim?

Mr. MENDELL. Yes, sir, I was part of that recall.

Mr. STUPAK. OK. And then in 2003, 2004, your company aggressively went after the, I shouldn't say after, sought the hot lunch program providing meat to the Federal government for a hot lunch, right?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. OK. And in 2005, you had a complete by U.S. Department of Agriculture for non-compliance in handling of animals?

Mr. MENDELL. Yes. We had one violation written by USDA, yes, sir.

Mr. STUPAK. OK. Do you have that report with you today?

Mr. MENDELL. Yes, I believe we do.

Mr. STUPAK. Can you submit it for the record so we can see it? The downer cow issue, you agree they are not supposed to be put into the human food supply chain, food chain, correct?

Mr. MENDELL. Yes.

Mr. STUPAK. And why is that?

Mr. MENDELL. Because they changed the regulation in '04, until '04 they were allowed in the food chain, not school lunch, but commercial trade. In '04 the regulation was changed.

Mr. STUPAK. And do you know why that was?

Mr. MENDELL. In abundance of caution for E. coli, salmonella and——

Mr. STUPAK. And mad cow disease, right?

Mr. MENDELL [continuing]. Mad cow disease.

Mr. STUPAK. And it was established then, was it not, that of the 15 cases of mad cow disease in North America, U.S., and Canada, 12 of the 15 were downer cows. Eighty percent of those cows related to mad cow disease were downer cows, is that correct?

Mr. MENDELL. I don't know those exact numbers but they sound right to me.

Mr. STUPAK. Are you aware of the report, I think everybody has it, Canada confirmed a new case of mad cow disease on February

26, the day you were supposed to testify, confirm mad cow disease still available?

Mr. MENDELL. Yes, I was aware of that.

Mr. STUPAK. OK. Are you also aware that mad cow disease, including the Jack-in-the-Box case, they don't surface until on an average 13 years, but up to 20 years later before mad cow disease may surface in a human?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. So the statement that there has been no illness because of this recall, we don't know that for at least on an average 13 years later because of the incubation period, correct?

Mr. MENDELL. That would be correct.

Mr. STUPAK. OK.

Mr. MENDELL. But we have—we have safeguards in there, sir.

Mr. STUPAK. Well, let us talk about safeguards.

Mr. MENDELL. All right.

Mr. STUPAK. You said on the video we showed, you never saw the cow, we call it the water boarding cow, the last cow.

Mr. MENDELL. The water boarding cow I had seen.

Mr. STUPAK. You had seen?

Mr. MENDELL. Yes.

Mr. STUPAK. And that was put into the kill chute and that was made part of the human consumption, was it not?

Mr. MENDELL. No, I saw the video.

Mr. STUPAK. You saw the video.

Mr. MENDELL. Yes.

Mr. STUPAK. So that cow that we referred to, it is at mark 435 in the video if you want to get it up, Kyle, that went into the food supply, did it not?

Mr. MENDELL. I am not sure if it did, sir.

Mr. STUPAK. Well, it went into the kill and it was killed. It showed that on the tape, does it not?

Mr. MENDELL. OK. Was that—yeah, I am not certain that was the cow, but yes.

Mr. STUPAK. OK. So that would be a direct violation, that cow as a downer cow could not go into the food chain, correct?

Mr. MENDELL. That would be a direct violation unless it was re-examined by a veterinarian.

Mr. STUPAK. Was it re-examined?

Mr. MENDELL. I don't know, sir.

Mr. STUPAK. In that video, did you see any veterinarian there?

Mr. MENDELL. No, it didn't look like it to me, sir.

Mr. STUPAK. OK. Kyle, do you have a second clip? Let me show you this clip. You said there was a second video you never saw.

Mr. MENDELL. Right.

Mr. STUPAK. But you talked to the USDA about it, correct?

Mr. MENDELL. I am sorry?

Mr. STUPAK. You said you talked—in your written testimony you said there is a second video, USDA called you on it, and that is when you decided to do the recall.

Mr. MENDELL. That is when they decided to recall.

Mr. STUPAK. And you've never seen the video?

Mr. MENDELL. I haven't seen that one, and I don't know if there is another one.

Mr. STUPAK. OK. Kyle, show the second one.

[Video.]

Mr. STUPAK. OK. Has your company ever illegally slaughtered, processed or sold a downer cow?

Mr. MENDELL. I didn't think we had, sir.

Mr. STUPAK. OK. The first video shows a downer cow going in the kill box, right?

Mr. MENDELL. Yes.

Mr. STUPAK. This last one was a cow that never made it to the kill box. It was there, not quite in, and they shot it and they dragged it in, correct?

Mr. MENDELL. That is the video that I hadn't seen that USDA had called me on, sir.

Mr. STUPAK. I am curious, and I know my time is up, but when seeing these videos, the first video was on the Web weeks before we had our hearing. This one has been on for a couple of weeks, the one you just saw. We download them off——

Mr. MENDELL. That one I never saw, sir. I thought it was——

Mr. STUPAK. Wouldn't your own curiosity as president of the company and CEO you are responsible for, wouldn't you want to see what is being played out there, what they are saying about your company, what the videos are showing about your company?

Mr. MENDELL. Yes, I would, sir.

Mr. STUPAK. So the recalls of the 143 million pounds of meat based upon these two cows we know went in was a proper recall then because of mad cow disease, correct?

Mr. MENDELL. It was a regulatory violation for sure. It was inhumane treatment for sure.

Mr. STUPAK. Let me just be real clear. There is no doubt that a downer cow since 2004 according to your testimony cannot be put in the nation's food supply because of concerns of mad cow disease, which does not manifest itself in human beings on an average of 13 years later, is that correct?

Mr. MENDELL. That is correct, unless you have a vet there to examine it, and I did not see a vet.

Mr. STUPAK. So based upon what we saw, it would be logical to conclude then at least two downer cows went into the nation's food supply as we did not see a vet make a physical inspection before it was put in the kill box?

Mr. MENDELL. That would be logical, yes, sir.

Mr. STUPAK. OK. So then let me take it one step further. The cow we just saw in video 2, the water board cow in video 1, they were illegally slaughtered underneath the rules and regulations of the United States?

Mr. MENDELL. Correct.

Mr. STUPAK. I have more questions, but my time is up. I will turn to Mr. Shimkus for questions, please.

Mr. SHIMKUS. Thank you, Mr. Chairman. So for the layman here, especially the second video, that was the kill box?

Mr. MENDELL. Yes.

Mr. SHIMKUS. OK. We just wanted to clarify that. Because the real issue here—there are two big issues. The one is, and the chairman has just highlighted the point ,is that your statement says it is not a food safety issue, now after having seen the second video

our issue is going to be downer cows in the kill box. The risk is greater than the ability to—I mean the risk is such that that is why we have the rules, no downer cows in a kill box because of the uncertainty of the food process. And so it is a food safety issue to us based upon the second film.

Mr. MENDELL. I believe those cows should be verified on a case-by-case basis by the USDA veterinarian. He has the authority to let that cow go or not.

Mr. SHIMKUS. I just want to clarify that because I am assuming that if a vet, and I could be wrong, I am not in the business, but if a vet had inspected it that would still give the authority of a processor to drag a cow that has been inspected into the kill box? I would assume it would have to walk—it would still—you would inspect it, it is OK, and then we escort it in instead of the—I mean dragging, that is my concern.

Mr. MENDELL. I believe the regulation states that that cow must be ambulatory to the knock box.

Mr. SHIMKUS. Thank you. Let me ask, the other concern is the whole idea is to protect the food safety of our citizens, and you go through a litany of regular training, compliance audits, interim audits, USDA audits, the review that was submitted and accepted for the record. The simple question is what went wrong, and if you have so many audits, and we have all be in businesses where we have audits and reviews. Is it a fact that heads-up were given to the processing facility so when the inspectors are there everything is above board, and when the inspectors leave everything returns to an operating process which is not acceptable? That is the follow-up question. You have done the auditing. What went wrong?

Mr. MENDELL. Well, obviously there was a breakdown in our training or our programs to allow that kind of behavior to occur.

Mr. SHIMKUS. But there is also wrong in the audit that you paid for, there is something wrong in all these reviews that someone—the concern from my aspect as a supporter of business and industry is the corporate culture. And you have so many reviews. Was there a corporate culture change that effected a nod and a wink to all these audits and a heads—that is the problem. We have to figure out why you had so many reviews, so many internal audits, so many inspectors, and then the Humane Society does their undercover and, voila, it is pretty graphic and it is not defendable.

Mr. MENDELL. It is very graphic. It is very sickening to me also. We also put videos in there after this occurrence. I think the only answer to solve this kind of problem are video cams. We installed 17 video cams shortly after that that covered every square inch of that yard and the unloading area, and paid a company, Aero Sight was the name of the company, for 24/7 surveillance along with Dr. Grandin and Dr. Voogood looking at them on a weekly basis check-up.

Mr. SHIMKUS. Let me just finish up because the major point is this has been devastating across the board. It is devastating to the treatment of the animals and we all accept that and are aggrieved by that. It is devastating because of the possible risk to the food supply, and again highlighting the mad cow disease and all the things that we are dealing with on food recalls we are under pres-

sure to get this right. And it is devastating to you personally, your family, all the employees.

Mr. MENDELL. Yes, sir.

Mr. SHIMKUS. The tax base, and we have to do what we can to try to make things right, so I lay that on the table that this is destructive to everybody and it is unfortunate and we got to try to find a way to fix it, so I appreciate the chairman—I yield back my time, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Shimkus. Before I turn you over to Ms. DeGette for questions—oh, sorry, Mr. Dingell is there. Let me just, a word of caution. On questions, your answers to my questions, page 2 of your testimony, you said I want to emphasize that thought that the activities shown on the video are not food safety. The cows shown in the video could not walk, were designated to be euthanized and were not put into commerce. I think we established that is not true based on your testimony. You also state these cows were not slaughtered, ground or sold. They were euthanized and removed. That may not have been true. That is what your written statement said, which is supposed to be under oath and part of the record, but I believe your oral testimony contradicted that. You may want to clarify that.

Mr. HUTCHINSON. It is an important point. The testimony that was submitted referred to an excerpt of a video that my client saw, and so his testimony was accurate relating to the excerpt of the video that he saw and his testimony is correct in that regard. It has obviously been clarified today in further testimony.

Mr. STUPAK. The only hesitance I have, Mr. Hutchinson, is the top of page 2, shocked with an electrical prodder, and had water hoses sprayed in their nose in an effort to get them to their feet. That was the one that was euthanized and put in the food chain, the one where Mr. Mendell said I was not aware of it, but that is the same one he saw. He describes it in his testimony. That had to be video number 1. It is the same. So the written testimony and the oral testimony are not on the same parallel. And I just caution. The committee is under oath for a reason and I want to—before I unleash Mr. Dingell, I just want to give you that caution.

Mr. HUTCHINSON. We appreciate the instruction of the chairman, and I think combined with what his statement has been for the record, both written and orally, I think he testified orally that provides a clarification and direct answers to the committee.

Mr. DINGELL. Mr. Chairman, I believe it is the custom for the committee to swear all witnesses, is that correct?

Mr. STUPAK. Yes. He was sworn in earlier with the——

Mr. DINGELL. Mr. Mendell has been sworn. The other gentleman——

Mr. STUPAK. He was identified and sworn early on, yes.

Mr. DINGELL. The other gentleman at the table, has he been duly sworn?

Mr. STUPAK. Mr. Mendell has. Mr. Hutchinson, have you been—you were sworn in the beginning, were you not?

Mr. HUTCHINSON. No, I was not.

Mr. STUPAK. OK. Then we are going to have to do it right now then, OK?

Mr. DINGELL. Mr. Chairman, my understanding of the practice of the committee that a witness has the privilege of being sworn and testifying. He has the privilege of having a lawyer and having the lawyer advise him during his appearance before the committee. I am not aware of any privilege that permits an individual to be sworn and to serve as a witness and yet at the same time to serve as an attorney or lawyer or legal advisor to the witness. I think Mr. Mendell has the privilege of being duly sworn and testifying. The gentleman there at the table, he is appearing here as a lawyer. It was always my practice when I ran the committee and this subcommittee that those who appeared as lawyers functioned as lawyers, and those who function as lawyers could not testify.

Mr. STUPAK. Point well taken, Mr. Dingell.

Mr. DINGELL. I believe that is the practice to which we should continue to adhere, and I think Mr. Mendell should be permitted to answer the questions, and if he can't then he should state so and we will decide whether or not we want to hear from his lawyer under oath at a suitable and proper time.

Mr. STUPAK. Very well taken, Mr. Dingell. In my sense of fairness in trying to make sure everybody is treated fairly here, I had asked Mr. Hutchinson a question or two. You are right, he cannot be a lawyer and a witness at the same time. Therefore, I would recommend and I would suggest to the committee with no objection that Mr. Hutchinson stays where he is at, not take the oath, but can advise Mr. Mendell. Before you answer a question if you want to consult with Mr. Hutchinson, we will give you that opportunity. I just want to make sure everybody is clear on where we are going, clear on the statements, clear on the facts because there are extenuating circumstances that may develop in this.

Mr. Shimkus.

Mr. SHIMKUS. I have no objection, Mr. Chairman. The only thing that I just want to get a handle on the line of questioning and maybe because I don't understand what I am seeing. There is an assumption here that in the first tape that there is a clear indication that a downer cow went into a kill box. I don't know if I need a rerun. I have a hard time seeing that. I am not sure. And I don't have to see the whole thing. It is just that last section where—because that is where a lot of confusion is. And then obviously the second film we are clear, we are clear there is problems with. I just have trouble—we saw that first film in the other hearing. I don't know if our line of questioning went in that direction that there was concern about the food safety supply then.

Mr. STUPAK. The other caution I had, Mr. Shimkus, and point well noted, but I had asked Mr. Mendell directly based upon what we saw, the first video, second video, and no veterinarian had looked at this cow. Would it have been illegal to put this cow in, and he answered yes. So that sort of cleans that one up, I think. Go ahead.

Mr. SHIMKUS. If the chairman would yield, I would like to pose—I think there is a lot of confusion and he has answered but I would ask it again for full clarification so we know on the first video food safety, kill box.

Mr. STUPAK. I had asked the question and let me take a minute and try to clarify this. Has your company ever illegally slaughtered, processed or sold a downed cow, Mr. Mendell?

Mr. MENDELL. Not that I was ever aware of.

Mr. STUPAK. Correct. And that was your answer earlier, you said not that you were aware of. And then I directed your attention to the video.

Mr. MENDELL. Correct.

Mr. STUPAK. And we discussed the fact that the water board cow went into the, I called it a kill box but I guess it is a knock box, and then once it went into that knock box it went into the food supply, and we established no veterinarian had looked at it which is required by law. And then we mentioned the second video where that cow was shot outside the knock box and then dragged into the kill box. That one went in on the second video. So the question I believe to the best of my memory I asked since 2004, since the rules changed in 2004, that downer cows could not go into the food supply for human consumption because of the concern of mad cow disease which manifests itself 13 years, maybe as high as 20 years later, as the reason why we do not allow downed cows into food supply, I think you answered affirmative to that, correct?

Mr. MENDELL. Yes.

Mr. STUPAK. And then I said so in summation at least two of these cows then that we saw in the video, the two videos, were illegally slaughtered. I believe your response was yes.

Mr. MENDELL. OK, to clarify that. The cow getting the water sprayed in its nose, that is clearly inhumane treatment. I did not see an inspector there to reinspect that cow to allow it to go into the food chain.

Mr. STUPAK. And we saw it go in the kill box, therefore, it went into the food chain?

Mr. MENDELL. Yes.

Mr. STUPAK. OK. And the second one, the second cow, that short video.

Mr. MENDELL. Yes.

Mr. STUPAK. Where they shot it outside the kill box, and then it went into the kill box, then it went into the food supply. It was not inspected by a veterinarian.

Mr. MENDELL. Not that I saw, sir.

Mr. STUPAK. So it is fair to say then that these two cows went into the food supply and that would be illegal since at least 2004 to put a downer cow in the food supply for human consumption?

Mr. MENDELL. I would say that it is a rules violation for not calling a USDA veterinarian to inspect that cow to either let it or not let it go in.

Mr. STUPAK. The veterinarian, even though the veterinarian could have rectified the problem, the problem is we have a downer cow according to the video that saw no veterinarian there went into the food supply. That is what makes it illegal, the downer cow being in the food supply, is that correct?

Mr. MENDELL. Yes. I don't have all the facts. I just see what I see on the video. I am not completely sure if that cow walked all the way in the knock box, or backed out of it, which is a common occurrence. There is a door that closes behind it.

Mr. STUPAK. But if the cow went into the food supply everyone can make their own conclusions from that video——

Mr. MENDELL. Yes.

Mr. STUPAK. We didn't see a veterinarian. If it went in the food supply that would be illegal.

Mr. MENDELL. Right. That would be illegal. It did go through postmortem inspection.

Mr. STUPAK. Right, but whether it went through postmortem or not, a downer can't go into the food supply. That is the law since at least 2004 in this country according to USDA and Federal law, correct?

Mr. MENDELL. Without approval of the vet.

Mr. STUPAK. Correct. And we didn't have a vet in——

Mr. MENDELL. I didn't see one, sir. It is a case-by-case basis, and I did not.

Mr. STUPAK. And in these two cases we didn't see a veterinarian?

Mr. MENDELL. I did not.

Mr. STUPAK. OK. All right, you are going to find this a hard one to believe but we have an air code yellow meaning a plane is within our air space. We need to evacuate the building. But not yet, not yet. OK. They are cautioning not yet. If we do, I am going to give you a 2-second warning. Leave calmly, OK? If you want to leave now, you can. There is a plane in our air space. We may need to evacuate. Now, Ms. DeGette—no, Mr. Dingell for questions, please.

Mr. HUTCHINSON. Mr. Chairman.

Mr. STUPAK. Yes.

Mr. HUTCHINSON. Mr. Mendell did have one clarification on that last question.

Mr. STUPAK. OK. Clarification before we go to Mr. Dingell.

Mr. DINGELL. Thank you. Mr. Dingell——

Mr. STUPAK. Mr. Dingell, one minute, please. Mr. Mendell wants to clarify something for us before I turn it to you, sir. Mr. Mendell.

Mr. MENDELL. If that cow did not pass postmortem inspection it would not have gone in the food supply either.

Mr. STUPAK. That is fine. Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy and I commend you again for these hearings. Mr. Mendell, in your statement—you make this statement at page 2. I want to emphasize though that the activities shown on the video are not a food safety issue. The cows shown in the video could not walk, were designated to be euthanized, and were not put into commerce. Then you said this. All these cows should be treated humanely. They were not. These cows were not harvested and they did not enter the food system. They were not slaughtered, ground or sold. They were euthanized and removed. Are we to believe that statement? The movie shows things rather differently.

Mr. MENDELL. Those were probably different videos, sir.

Mr. DINGELL. Sorry?

Mr. MENDELL. They were probably a different video, sir. I have seen clips of different videos, 50 of them. I have not seen what I saw here today. I saw pieces of it. I have never seen the whole thing.

Mr. DINGELL. So we have to assume then that your statement here is incorrect, is that right?

Mr. MENDELL. Not based upon the video that I saw, sir.

Mr. DINGELL. All right. Now, Mr. Mendell, I have got to say I have certain sympathy for you because you are not in a very pleasant place but I have a few questions more that have to be directed to you. You chose not to attend the hearing on the invitation of the committee on February 26, and despite substantial efforts by the committee staff to reach you, you avoided the committee staff. Now will you explain to me why you chose not to appear before the committee and why it was necessary for the committee to subpoena you for your presence today?

Mr. MENDELL. During the last—during the last committee meeting, I was on the recall team at Westland Meat Company. My company was in a crisis. It was next to impossible for me to leave, sir. I apologized to the committee earlier for that, and I deeply regret not being able to attend, but this was a very serious incident. I was trying to comply with USDA.

Mr. DINGELL. You did not so communicate this to the committee or the staff as they communicated to you, is that correct? You didn't advise the committee of these matters, did you?

Mr. MENDELL. I said that I was over-inundated with phone calls, news reporters, and my business was in the middle of the biggest recall in U.S. history, and I didn't want to leave my recall staff without me.

Mr. DINGELL. Now, Mr. Mendell, in your testimony you state, and I quote, "The company does not pay suppliers for the cost of a cow deemed unfit for human consumption and there is therefore no financial incentive to bypass the regulations." I would note here that the pictures—so you are telling us here that you don't pay these people for these downer cows, so you got a whole bunch of downer cows going in, and we have pictures of them. I must assume then that you didn't pay for these downer cows but the downer cows were put into the food supply according to the pictures which we saw. Now that leaves me then with the assumption that you are not paying for these downer cows but the downer cows are winding up in the food supply and causing recalls of meat because of the improprieties that have been associated with the slaughter and with the slaughter of downer cows. Am I correct or incorrect with that?

Mr. MENDELL. That is incorrect, sir. Those cows——

Mr. DINGELL. What are the facts then, if you please?

Mr. MENDELL. Those cows are—each one of those cows has a number on them. If that number—those numbers are recorded through that plant. If that cow goes in the plant it is paid for. If it is processed and it passes postmortem inspection it is paid for. Any cow that we euthanize in a truck, in a pen, any place outside the plant, usually most of the time those cows are bought as a subject or on the rail and they are not paid for. There are instances where our buyers buy some. They are euthanized or they don't pass inspection, we do pay.

Mr. DINGELL. Now in your statement, Mr. Mendell, you told us the number of times that you had been audited by USDA.

Mr. MENDELL. Yes, sir.

Mr. DINGELL. And I am assuming that in each one of those audits you got a clean bill of health, is that right?

Mr. MENDELL. Yes, sir.

Mr. DINGELL. So you then—I would note, however, before you owned Hallmark Meat Packing Company, Hallmark faced scrutiny for the way it handled downer cows. Were you aware of the problems that the company had before your ownership of it?

Mr. MENDELL. No, sir.

Mr. DINGELL. And I would note that during that time you owned Westland Meat Company, which bought beef from Hallmark, is that correct?

Mr. MENDELL. On occasion, yes, sir.

Mr. DINGELL. Did you have any awareness then of mishandling of downer cows and the handling of downer cows by Hallmark either through yourself and your own knowledge or that of your company, Westland Meat Company?

Mr. MENDELL. Not at that time, sir.

Mr. DINGELL. So all during that time the Department of Agriculture is giving you clean bills of health in its audits of your company and in its audits of Hallmark. I wonder if you could help us to understand why did they do that if we had all these problems that were going on during that period of time?

Mr. MENDELL. Well, the only problem I know we had, sir, was the inhumane treatment of animals and obviously my system broke down. I don't know how often USDA is supposed to be in a knocking box or examine the yard areas or loading or unloading. I am not really sure, sir. Obviously, my programs, which is very disappointing to me after extensive training and hours and hours and hours of training, obviously failed.

Mr. DINGELL. Thank you, Mr. Mendell. Mr. Chairman, I thank you for your courtesy.

Mr. STUPAK. Thank you, Mr. Dingell. Mr. Whitfield for questions.

Mr. WHITFIELD. Thank you, Mr. Chairman. And, Mr. Mendell, thank you for being with us today. I want to, first of all, just go over a couple of things regarding the Washington Post article about this. Now you are the chairman or you are the owner of this slaughterhouse, is that correct?

Mr. MENDELL. I am the owner of Westland Meat Company and I manage Hallmark Meat Packing.

Mr. WHITFIELD. OK. And how many plants do you have?

Mr. MENDELL. One plant.

Mr. WHITFIELD. Just one. And what is the status of that plant today?

Mr. MENDELL. It is closed.

Mr. WHITFIELD. And do you anticipate that it will be reopened?

Mr. MENDELL. I doubt it, sir.

Mr. WHITFIELD. OK. Now I think it is very clear to everyone that there are a couple of issues here, 1, the humane slaughter of animals, and, 2, the food safety chain. And you have been pretty straightforward today in saying that this was inhumane treatment of these animals so there is no question about that. And I notice that when you first saw these videos you made the statement that it is impossible, electrical prods are not allowed on our property, and it is absolutely not true that water was sprayed at the nose of these animals and that we have a massive humane treatment program that we follow to the nth degree. All of those statements

turned out not to be correct, but you have admitted today that whatever the procedures that you had in place, they simply did not work, is that correct?

Mr. MENDELL. Yes, sir. Evidenced by the audits that I received from USDA and all these third party audits, and I knew the programs we had in place. I knew the training that we had in place. I mean I couldn't believe that it was my plant until I saw the video.

Mr. WHITFIELD. Now you mentioned that video cameras are really the only way to ensure a clean plant, a humane plant, and so forth, and you installed those cameras at this plant, is that correct?

Mr. MENDELL. Yes, I did, sir.

Mr. WHITFIELD. Now in your knowledge of other owners of slaughterhouses, do most slaughterhouses have cameras installed?

Mr. MENDELL. No, sir, they do not. I only know of one.

Mr. WHITFIELD. And you know we have a lot of Federal laws relating to criminal charges against people who treat animals inhumanely, as an example, Michael Vick recently, and it is my understanding that current Federal law does not provide for criminal penalty even in cases of the egregious offenses for violation of humane handling at slaughterhouses. Is that your understanding as well?

Mr. MENDELL. I am not sure of that law, sir.

Mr. WHITFIELD. So you don't know if there are any criminal violations here or not under existing Federal law?

Mr. MENDELL. I know that the county of San Bernardino has charged the two employees that we fired with criminal charges.

Mr. WHITFIELD. OK. Now when a load of cattle arrives at the plant do they normally arrive in double deck trailers?

Mr. MENDELL. The majority, yes, sir.

Mr. WHITFIELD. And these are cattle that you have buyers that have gone out and purchased or you have contracts with suppliers that just bring them in?

Mr. MENDELL. Both.

Mr. WHITFIELD. And when the cattle arrive at the plant is there an inspector when they are unloaded from the trucks?

Mr. MENDELL. No. Not purposely, unless, not unless he is doing antemortem inspection.

Mr. WHITFIELD. But the inspection is the responsibility of the Department of Agriculture, is that correct, or do you have the——

Mr. MENDELL. I am not sure if that is the regulation for them or not, sir.

Mr. WHITFIELD. Well, the postmortem and antemortem, whose responsibility is that?

Mr. MENDELL. That is theirs.

Mr. WHITFIELD. OK. So you are saying you don't know if they have a responsibility to inspect the animals when they are unloaded from the trailers?

Mr. MENDELL. No, sir.

Mr. WHITFIELD. The only thing that you are really aware of is that they do have ante- and postmortem inspection responsibility?

Mr. MENDELL. Yes, sir.

Mr. WHITFIELD. And they also supply a veterinarian that even on the downer cow can approve that animal for slaughter, is that correct?

Mr. MENDELL. Could you ask me that one more time, sir?

Mr. WHITFIELD. The Department of Agriculture provides a veterinarian that comes to the plant and if they inspect a downer cow and decide that it is OK to be slaughtered then it can be slaughtered, is that correct?

Mr. MENDELL. Yes.

Mr. WHITFIELD. And the only mad cow—most of the mad cow disease that has occurred in the U.S., there hasn't been that many, has been directly related to downer cow, traced to a downer cow, so what would you think about—I recognize the monetary situation but it seems to me that maybe we should have a blanket policy that downer cows will not be slaughtered. Do you have an opinion on that?

Mr. MENDELL. Well, I think they should take them on a case-by-case basis but the vets—maybe they don't have enough vets. Maybe they aren't staffed properly. I am not sure. I couldn't answer that question.

Mr. WHITFIELD. But on the downer cows at your plant on this particular day, we do not really know if a veterinarian was there or not, is that correct?

Mr. MENDELL. It didn't appear in the video, sir, but he could have been there earlier. We could have shot five earlier. We could have euthanized five earlier that day when he was there. I am just not positive.

Mr. WHITFIELD. But the USDA inspectors, they do not stay at these plants. They just come and go?

Mr. MENDELL. No, sir. They are stationed at my plant, 5—4 or 5.

Mr. WHITFIELD. And how many of the inspectors are stationed there?

Mr. MENDELL. I believe there are four inspectors and one vet, if I am not mistaken.

Mr. WHITFIELD. And they are there all the time?

Mr. MENDELL. Yes, sir.

Mr. WHITFIELD. All day long?

Mr. MENDELL. Yes, sir.

Mr. WHITFIELD. OK. I see my time has expired, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Whitfield. Mr. Green for questions, please.

Mr. GREEN. Thank you, Mr. Chairman. And again, Mr. Mendell, we appreciate you appearing today. And I guess all of us have been touched because I have two school districts in my district in Houston, Texas, Pasadena Independent School District and Houston Independent School District, who bought meat from your plant and were part of that recall. Now I have to admit why would a Texan buy meat from California but we will talk about that later. I do have some questions. One, in light of the videos that you saw was the recall justified especially considering the latency time for mad cow disease?

Mr. MENDELL. I think—I think the decision for the recall was made in a matter of 4 or 5 hours, if I am not mistaken. I think

in my humble opinion that USDA could have contacted Alameda, our local area office, talked to the veterinarian in charge, talked to my area supervisor, and thought about this a little bit before the recall. We do have safeguards in place, sir, with specified risk material which are known to harbor the prion of Mad Cow. We do remove that from every beef that we slaughter. We are the—the USDA is currently trying to lift age limitations on beef going to Japan and Korea because of specified risk material removal. We have that same process in place.

Do I feel it was enough of a safeguard? Yes, I do. That is why we have the program in process. That is why the USDA has it in process to move that specific risk material. So if a downer got into the system, that harmful part of that cow has been removed.

Mr. GREEN. Let me ask you because again I haven't spent as much time maybe as you have but since the downer cows, the solution would be to put video out there and not just a supervisor overseeing those employees, how do you know that your program was carried through to remove that part of that cow?

Mr. MENDELL. It is documented inside the plant and audited as well, I see your point, it is audited as well inside the plant. I believe it is a lot easier to audit it inside than outside.

Mr. GREEN. Well, I read your testimony and I know you had audits both inside and outside, but I also assume that the outside where those downer cows were taken in when they shouldn't have been that you had oversight and you had audits there?

Mr. MENDELL. Yes, we have.

Mr. GREEN. OK. So that system failed, and I would be concerned about the latency period on mad cow disease, and I think that is the concern that the FDA—and we have learned now from the FDA that oftentimes they don't respond very quickly whether it be toy safety or other things—not toy safety, that is consumer product, but other issues. But let me ask another question. One of the pen workers who has been charged criminally in this case stated that he felt pressured to ensure that a certain number of cows were slaughtered each day. If he didn't meet that quota that management was angry. Is this true?

Mr. MENDELL. No. I mean we had a—we harvested 500 cattle a day. Yes, did he have to do his job, did he have to do it in a timely manner? Yes. I had pressure selling it too. Everybody that worked there, I mean, had pressure. Do I think it would be an excuse to inhumanely treat an animal? Absolutely not.

Mr. GREEN. In 2005 USDA cited your company for non-compliance for being overly aggressive and using electric prods to move cattle. What corrective actions did you take?

Mr. MENDELL. Well, we rewrote our programs immediately, retrained our employees immediately, and we also used a different kind of—yes, it is not—I think the recommendation by Temple Grandin, the authority on this, was 50 volts. We use 6 volts, the battery packs. It is not—we used it excessively. I think we used it 8 percent more than we were supposed to, 8 out of 100 cows more, if I am not mistaken. You are allowed to hit 25 of them. I think we did 33. I believe, if I remember correctly.

Mr. GREEN. OK. So that was the 2005 incident?

Mr. MENDELL. Yes, sir.

Mr. GREEN. Were there any other incidents of non-compliance from the USDA?

Mr. MENDELL. Not that I recall, sir, no.

Mr. GREEN. I guess, having supervised employees and you had many more than I had to when I was in business, but I guess the supervisors are supposed to report—you can put video—videoing the employees, videoing the supervisors, but again it seems like somebody who was in management overseeing what was happening, and that should have been reported or maybe they were encouraged by the production too much because we see this in a lot of companies that are obviously in different types of businesses, and so I guess that is my concern about it. And the recall was maybe unjustified in your sense but I am not so sure any of those children in my district that consumed any of that meat if they did, 13 years from now or 10 years from now, you are not going to be around to deal with that so that is the concern that I think our whole committee and this Congress has on a bipartisan basis. Thank you, Mr. Chairman. I know I am out of time.

Mr. STUPAK. Thank you, Mr. Green. Ms. DeGette, for questions.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Mr. Mendell, you said in your testimony that in 2005 you had a violation for mishandling of animals, is that correct?

Mr. MENDELL. That is correct.

Ms. DEGETTE. Did you recall any of your product at that time?

Mr. MENDELL. No, ma'am.

Ms. DEGETTE. So what was the financial result for your company of that violation in 2005?

Mr. MENDELL. Financially, none.

Ms. DEGETTE. Yes, there was none. Did you install video cameras after that violation in 2005?

Mr. MENDELL. No, I didn't.

Ms. DEGETTE. No, you didn't. What other further steps did you take in 2005 to increase the surveillance over the handling of the animals?

Mr. MENDELL. I don't believe we increased surveillance. We rewrote our programs and retrained our employees and went on an aggressive monthly training program with all of our employees.

Ms. DEGETTE. OK. And then after the recall in 2007, what was the financial impact on your company then? I am sorry, 2008, this year.

Mr. MENDELL. It is devastated.

Ms. DEGETTE. What is the price figure for devastated?

Mr. MENDELL. I couldn't imagine.

Ms. DEGETTE. Hundreds of millions of dollars?

Mr. MENDELL. Yes, ma'am.

Ms. DEGETTE. And after that, then you installed the video cameras, correct?

Mr. MENDELL. Yes, ma'am.

Ms. DEGETTE. And how much did that cost you?

Mr. MENDELL. Oh, yes, I did do the video cameras before I knew there was going to be a recall. I am sorry.

Ms. DEGETTE. When did you do the video cameras?

Mr. MENDELL. When we realized there was inhumane treatment.

Ms. DEGETTE. Well, when was that? You learned, I think, according to your written testimony, you learned about the videotape in early February of this year, so when did you install the cameras?

Mr. MENDELL. I think we ordered them within the next 3 or 4 days.

Ms. DEGETTE. OK. And how long after you learned about the videotape did you hear from the U.S.—so at that time even though you knew about the videotape and the treatment of the animals, you did nothing, your company did nothing to voluntarily recall the beef, did you?

Mr. MENDELL. No.

Ms. DEGETTE. In fact, it wasn't until you heard from the USDA about the second tape, and when they urged you to do a voluntary recall that you then complied with that voluntary recall, right?

Mr. MENDELL. That is correct.

Ms. DEGETTE. So how long after learning of the first tape did you learn about the second?

Mr. MENDELL. I believe the second tape we didn't hear or see, and I haven't seen it until today. I don't think we heard about the second tape for about 10 days.

Ms. DEGETTE. Ten days after the first tape?

Mr. MENDELL. Yes, ma'am.

Ms. DEGETTE. And so what your testimony is that you ordered the video cameras after the first tape but before the second, correct?

Mr. MENDELL. Yes, ma'am. When we realized there was an inhumane issue, we thought it was the only way that we could resolve it, and we went ahead and installed them.

Ms. DEGETTE. OK. Now, so have you ever recalled product before, sir?

Mr. MENDELL. No.

Ms. DEGETTE. And have you ever been advised by the U.S.—so in 2005 you didn't recall any product, correct?

Mr. MENDELL. I am sorry?

Ms. DEGETTE. In 2005 when you received the citation from the USDA for mishandling of animals, you did not recall any product, correct?

Mr. MENDELL. No, ma'am.

Ms. DEGETTE. OK. Now I want to ask you of the downed cows that we have seen in the videotapes today which at least the committee believes entered the food supply, would a consumer going into a grocery store be able to know or a school serving this beef in a school lunch be able to know whether meat from that cow or from that lot of cows was in the meat that was being served in their facility?

Mr. MENDELL. Not that exact cow, no.

Ms. DEGETTE. Would they be able to know about the cows from that lot whether they were in the meat that was being served?

Mr. MENDELL. Yes.

Ms. DEGETTE. How would they know that?

Mr. MENDELL. They would know—we have a lotting system that every 60 cows is a lot.

Ms. DEGETTE. So what happens after that lot then goes to be processed?

Mr. MENDELL. Well, it is documented. We can tell where that lot came from. We know whose cows are in that lot——

Ms. DEGETTE. Well, you know which cows are in the lot when you send it to be processed, correct?

Mr. MENDEL. Yes.

Ms. DEGETTE. And then what happens to that lot number after it is sent to be processed, say, into hamburger?

Mr. MENDELL. I believe we still maintain that lot. I think we can trace——

Ms. DEGETTE. OK. But do you know whether that lot information is contained—because when they make hamburger, I am sure you know this, you are in the business, and I am just a congressperson, but when they send the lots of cows to the processors to be processed into hamburger they take meat from a number of different lots, correct?

Mr. MENDELL. No, those lots—well, yes.

Ms. DEGETTE. Yes, they do.

Mr. MENDELL. Four or five lots mixed in that one——

Ms. DEGETTE. Exactly.

Mr. MENDELL. Yes, exactly.

Ms. DEGETTE. And there is no federal requirement right now that the numbers from those lots that are mixed into that hamburger be documented which lots went into that hamburger, did you know that?

Mr. MENDELL. Yes, I do know that.

Ms. DEGETTE. So, therefore, when the person at the local elementary school or when the consumer at Safeway buys a package of ground beef they would have no idea whether the cows from the lot that were downed cows at your plant were contained in that package of hamburger, correct?

Mr. MENDELL. Correct.

Ms. DEGETTE. And from what you are saying, you document which cows go into which lot, correct?

Mr. MENDELL. Correct.

Ms. DEGETTE. And you document then which lots go to the processing facilities, correct?

Mr. MENDELL. Well, I have a processing—I make ground beef inhouse.

Ms. DEGETTE. OK.

Mr. MENDELL. The same building.

Ms. DEGETTE. So you would have the ability then——

Mr. MENDELL. To trace back.

Ms. DEGETTE. To trace back, correct?

Mr. MENDELL. Yes, ma'am.

Ms. DEGETTE. And that would probably help you financially in your business because if some ground beef was discovered that had salmonella or E. coli or whatever it could be traced back to that particular lot and then you could figure out what happened and you could recall that amount, correct?

Mr. MENDELL. Yes, ma'am.

Ms. DEGETTE. And that is probably easy to do within the industry, isn't it?

Mr. MENDELL. It is easy to do with a single source supplier like myself because I don't bring meat from the outside. It is all my

beef. If it is a stand alone grinder, they might buy meat from 10 different people.

Ms. DEGETTE. But they could still figure out those lots, couldn't they?

Mr. MENDELL. They could figure it out, and it would be a lot harder, yes.

Ms. DEGETTE. OK. Thank you very much.

Mr. STUPAK. Mr. Burgess for questions, please. We have a vote on the floor. There is 12 minutes left. As far as I know, it is only a motion to adjourn. Mr. Shimkus and I are going to stay. We will skip that vote. We want to keep this hearing going.

Mr. BURGESS. What about the plane, where is it?

Mr. STUPAK. Now it is code green. I think they are sending up little drones or something.

Mr. BURGESS. Mr. Mendell, thank you for being here today. I know it hasn't been easy to do this. I certainly respect the fact that you could have declined to be here today or declined to testify but you willingly gave your testimony, and we on the committee are deeply appreciate of that. On the second tape which this morning I guess you saw for the first time, do you have any reason to believe that the USDA or the Humane Society didn't share that tape with you? Do you feel you had the availability to view all of the tapes beforehand that were collected in evidence?

Mr. MENDELL. No, I don't.

Mr. BURGESS. Why wouldn't you have? Why would that have not been made available to you by the USDA?

Mr. MENDELL. I don't know. I asked them for it the night that they suggested the recall, and they said we will see what we can do about getting you the tape. I have yet to get it.

Mr. BURGESS. Now the recall, according to testimony we are going to get a little bit later, that was February 4, is that right, so some time much earlier in the month?

Mr. MENDELL. Yes, sir. I can't really remember.

Mr. BURGESS. Well, obviously this story hit the press wires and you became aware of it before that time. Were you aware of how animals were—if animals were mistreated in the process of going through the line there at the slaughterhouse?

Mr. MENDELL. At my plant?

Mr. BURGESS. Yes, sir.

Mr. MENDELL. No, sir.

Mr. BURGESS. Do you ever go out and watch the process yourself?

Mr. MENDELL. Occasionally. Not very often.

Mr. BURGESS. Do you think other CEOs at other packing plants would frequent the yards where this activity is taking place?

Mr. MENDELL. I doubt it.

Mr. BURGESS. I do too. Now I think in response to a previous question, some of the blatant violations were missed by 17 outside audits. Was your company aware of when audits would take place? Did you have any special preparation to be able to get through those audits?

Mr. MENDELL. I think we were occasionally notified and occasionally not. I couldn't tell you exactly. It really wasn't something I dealt with but——

Mr. BURGESS. Because it had never been a problem?

Mr. MENDELL. I don't think—no. I think USDA audits are sometimes announced, sometimes not announced, depending on where they want to go, what they want to—they might go to outside storage. They might want to—so they might call to arrange that.

Mr. BURGESS. On the subject of the violations that occurred, and you said they were blatant violations and not part of the company policy, I couldn't help but notice on the little bit of tape that we heard today the fact that I guess there might have been a language barrier. Were efforts made so that employee training was given in an appropriate language so that there would be no question about everyone understanding what their roles and duties were?

Mr. MENDELL. Yes, sir. We had bilingual supervisors.

Mr. BURGESS. Prior to this story breaking in February, and prior to the activity of this committee, at any point did you think there was a threat to public health at your plant?

Mr. MENDELL. No, I didn't, sir, not as evidenced by these audits and the amount of testing we were doing, no.

Mr. BURGESS. Do you think it was within your power as president of your company to prevent these activities from occurring?

Mr. MENDELL. The inhumane treatment?

Mr. BURGESS. Yes.

Mr. MENDELL. Yes, I think it should have. I think it was an oversight by me. Did I think I needed to with the training that I had in place? No. In hindsight, I wish I would have had cameras out there.

Mr. BURGESS. So your company cameras have now been placed were actually after the fact?

Mr. MENDELL. After the fact, sir.

Mr. BURGESS. Just one other observation that came up during earlier testimony when you weren't here in the previous hearing that there was some delay between the time that the Humane Society made the tapes available to the district attorney and the time that they then went public with their information and some concern on my part, and I think some other members had some concern about that delay that allowed more product to go into the stream of commerce. Had you been aware of those videos much earlier when they were made in October, early November, would that have diverted this material from the stream of commerce?

Mr. MENDELL. Would it have diverted——

Mr. BURGESS. Would it have prevented the potentially defective product from entering into the lunch menu?

Mr. MENDELL. Absolutely. If I knew that that was going on and we—I mean I couldn't believe that it actually was until I saw the videos. I would have put the cameras in—I would have put the cameras in immediately. Yes. Yes, I think it would have diverted the whole thing.

Mr. BURGESS. So the delay for whatever reason, whether it was the DA telling the Humane Society not to go public, for whatever reason the delay then compounded the problem?

Mr. MENDELL. Yes, sir.

Mr. BURGESS. Thank you, Mr. Chairman. I will yield back.

Mr. STUPAK. Thank you, Mr. Burgess. Ms. Schakowsky for questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I am very concerned because Chicago public schools were among those that received the meat. I represent a good part of the city of Chicago. I am also concerned about your testimony which I think I understand now essentially you revised your testimony where you say that there was not a food safety issue, that they were not slaughtered, ground or sold. That is not correct based on what you have seen, is it?

Mr. MENDELL. On the videos that I have seen, no. They weren't processed on the videos that I had seen. The two I saw today, they did go in the plant.

Ms. SCHAKOWSKY. What I am trying to understand is how you want to—you were so certain in your testimony having said that you yourself had not done any individual inspections. When you wrote this testimony you seemed absolutely certain that they were not slaughtered, ground or sold, that they were euthanized and removed, that there was not a food safety issue. How could you have felt so certain about that?

Mr. MENDELL. Based on the videos I have seen—that I saw, I did not think those cows went into the food supply, and I still say today that with our specified risk removal materials that is why it is a stage 2 recall with a remote possibility for health concern. They said that they played with a stage 3 recall was USDA's words, which I don't really know what the definition of that is. I know that the product has been fully tested and it has gone through every rigorous test that USDA had inside that plant. I think there is less than a minute chance of that product being contaminated.

Ms. SCHAKOWSKY. Would you say unequivocally under oath on the record then that there has not been in the past—now, aside from those cows that were on the video—that your plant has not had any food safety issue?

Mr. MENDELL. Not that I have ever been aware of, ma'am.

Ms. SCHAKOWSKY. Well, that is what I am concerned about. You say this is not the company I know. That is what you said in your testimony.

Mr. MENDELL. No, ma'am, it isn't.

Ms. SCHAKOWSKY. But what I question is, is this a company that you know? And I want to ask a question about the training. You said according to your testimony "the two fired employees as well as the Humane Society employee have participated in extensive training and retraining." However, according to the Wall Street Journal the Humane Society employee told the Chino police that he "had received no formal training." According to the article, on his first day the Humane Society employee reported to Pablo Salas, a manager who told the new employee not to be cruel to animals, but Mr. Salas only came outside to the pens 15 to 20 minutes a day. It was also reported that Mr. Salas put intense pressure on the pen managers to meet a quota of 500 pounds per day. So I want to know what your definition of extensive training and retraining is and why there was—or is there, I understand there is no certification process to confirm that employees had been trained, and how can you argue that your compliance audits worked when it is so clear that they failed?

Mr. MENDELL. OK. The training—I have two training documents here from Sean Thomas, which was the Humane Society employee. One is dated 10/8 and one is dated 11/12. He worked there 6 weeks. He had orientation. He had gone through the training process twice, and I have his signature here stating that he did so.

Mr. STUPAK. Mr. Mendell, are you going to offer those as exhibits? Are you going to offer those?

Mr. MENDELL. Yes.

Mr. STUPAK. OK. Kyle, can we get someone to make copies so we have them. You can go ahead, Ms. Schakowsky.

[The information appears at the conclusion of the hearing.]

Ms. SCHAKOWSKY. And I appreciate copies of the documents. So you are saying that that statement was inaccurate and false that he was not trained?

Mr. MENDELL. He was trained, ma'am.

Ms. SCHAKOWSKY. You have documents that say he was?

Mr. MENDELL. Yes, ma'am.

Ms. SCHAKOWSKY. OK, and that you are going to present. Let me ask one more question. According to their testimony on the Humane Society employee's first day on the job he saw a cow collapse on the way into the stunning box, and after she was electrically shocked and still could not stand, she was shot in the head with a captive bolt gun and then dragged on her knees into slaughter. I want to know, would you consume meat from a cow that was slaughtered in this manner?

Mr. MENDELL. No. It is against USDA regulation. Do we have video of that one or was that a statement he made? He made a statement that he didn't get training too, and we have documentation of that.

Ms. SCHAKOWSKY. Assuming that it all jives together, that in fact when he signed that that he actually did go through that training. I understand. You say you have documentation. My concern is that you refer to audits, you refer to policies, you refer to documents, and yet in just over a month of someone taking videotape the experience on the ground there was quite different from what you said. And I understand, you say you regret now that there weren't cameras. I think what we are concerned about is the discrepancy between things that are on paper, statements that are part of your policy, but that in reality we are seeing something very different and it is our job to try and figure out how to jive those two together. Thank you.

Mr. STUPAK. Thank you. We will continue with questions, another round. Mr. Mendell, Mr. Burgess asked you about the Humane Society, and without the work of the Humane Society we never would have known what went on in those days, correct, in November there with the downer cows being put in—without their work, we never would——

Mr. MENDELL. Without the tape, would I have known? No.

Mr. STUPAK. Anyone, no one would have known?

Mr. MENDELL. No, sir.

Mr. STUPAK. You indicated in your statement that you would have terminated these employees immediately. In your employee handbook if they put a downer cow into the kill box or a knock box

as you call it, does your discipline—is it very clear you are terminated?

Mr. MENDELL. They would have been terminated immediately for that too.

Mr. STUPAK. Is that in writing in your company policy?

Mr. MENDELL. Yes, sir. I don't think we have it with us, but I can gladly get the committee a copy. It is very clear, let us put it that way.

Mr. STUPAK. Mr. Burgess asked you about the health risk, and the safest way to protect Americans is just not put a downer cow into the human food chain, right? That is the safest way?

Mr. MENDELL. Yes.

Mr. STUPAK. You indicated that about the recall that you had 4 or 5 hours, you indicated earlier in testimony you might have seen 50 different videos, but yet the video we have seen today you hadn't seen those. Those were in the public domain a month before the—I shouldn't say that, a couple weeks before the February 26 hearing, and here we are, March 11, 12, so they have been out there for about a month.

Mr. STUPAK. Would there have been anything that would have prevented you from going online to look at these videos? You are the only one in America who hasn't seen it.

Mr. MENDELL. Maybe not. Maybe there wasn't anything that prevented me but I was in a crisis mode at that time. There were a million things going on with USDA. We were all being interviewed by USDA.

Mr. STUPAK. All right, but this is—the first video is 5 minutes. The other one we showed you is 1 minute. Six minutes. These videos were the accusations against your company. I would think you would want to say, man, what are they saying or what are they doing?

Mr. MENDELL. Well, I never saw the narrated video like that, not one time. I have never seen it. Like I said, I have seen——

Mr. STUPAK. I just find it amazing you would never look at it, that is all.

Mr. HUTCHINSON. Mr. Chairman.

Mr. STUPAK. Yes.

Mr. HUTCHINSON. May I just add perhaps as counsel, I was not aware that the last video——

Mr. STUPAK. You can't testify though, remember?

Mr. HUTCHINSON. I don't mean to testify. I am just saying we are not aware——

Mr. STUPAK. It is called testimony though. OK. Tell Mr. Mendell and Mr. Mendell can relay your answer. Let me ask you this. You said it was a stage 3 recall, I think you said, and you said you didn't know what stage 3 was.

Mr. MENDELL. I didn't know the definition of a stage 3.

Mr. STUPAK. OK. Do you know what it is today?

Mr. MENDELL. No, sir.

Mr. STUPAK. That is the possible highest risk. That is why it is stage 3. That is my understanding. Let me ask you this. What did they say if you—that they would make you do the recall. You said you had 4 to 5 hours. You had never seen the video. They said they had more video. You said you didn't see it. What convinced you

then to go along with the recall or was this a mandated recall by USDA that you had no choice?

Mr. MENDELL. Well, it is not mandatory, sir.

Mr. STUPAK. Right.

Mr. MENDELL. In 10 days it would be. That is what they told me the next morning. We consulted——

Mr. STUPAK. Didn't you ask them what is the basis of you forcing me, USDA, why are you forcing my company to go under recall if there is no risk and you have never seen downer cows go into the food supply?

Mr. MENDELL. We did ask them. They said it was based on a video, based on testimony of an employee. We asked who the employee is. They said they couldn't tell us. We asked for a copy of the video. They said they would see what they could do about getting it to us. That they thought there was enough evidence to——

Mr. STUPAK. And if this video and what they represented to you was going to devastate your company, as it has, as you have indicated——

Mr. MENDELL. Yes.

Mr. STUPAK [continuing]. And you had a 10-day window period, why wouldn't you just wait to see the video to make sure that they are not blowing smoke?

Mr. MENDELL. Would you think USDA would do that, sir, in this kind of an arena?

Mr. STUPAK. Well, from where I sit, absolutely. Your whole future, your whole——

Mr. MENDELL. Yes, my whole life up in smoke.

Mr. STUPAK. It just seems to me and some of us up here, there has to be something more there. I guess we are trying—is there something more? Are we missing something? You didn't see a video? You didn't go online? You didn't take time to even see the video and, say, at least present the video before I make a decision?

Mr. MENDELL. I had seen clips of the video, sir. I was called at 9:00 or 10:00 at night when this recall committee—9:00 or 10:00 west coast time.

Mr. STUPAK. OK.

Mr. MENDELL. They acted like I didn't have a choice, and I don't think I did. They said they would have sanctions in 10 days. It would be an involuntary recall and it would be worse.

Mr. STUPAK. How about then after you made your recall before you come to testify here, why wouldn't you have watched the videos then that were online to get prepared for testimony?

Mr. MENDELL. I had seen enough to be—I was regrettable enough with the videos that I had seen on the inhumane handling. I knew what the issue was.

Mr. STUPAK. Let me ask you this because it is part of our hearing. Does your company use carbon monoxide in your packaging of meat?

Mr. MENDELL. No.

Mr. STUPAK. Has your company ever used irradiation?

Mr. MENDELL. One more time?

Mr. STUPAK. Irradiation, have you used it?

Mr. MENDELL. Do I know about it?

Mr. STUPAK. No. Have you used it in your——

Mr. MENDELL. No, I haven't. We were about to. We never did.

Mr. STUPAK. Can a school district receive a refund? A number of the members mentioned refunds. They had to throw out their meat. Can they receive a refund from your company? I have probably about 20 school districts in my district.

Mr. MENDELL. I am not sure if that is going to be possible.

Mr. STUPAK. OK. In the Silliker report, this is one of these audit reports you want to put in there, on page 2 of the Silliker report it says animal welfare audit, beef. The video indicated that the inspections took place at 6:30 in the morning and 12:30 p.m. Do you remember that?

Mr. MENDELL. No.

Mr. STUPAK. OK. The narrative part of the first video.

Mr. MENDELL. 6:30 a.m. and 12?

Mr. STUPAK. Right. The video in the narrative said they started the inspections at 6:30 every morning. 6:30 was the inspection, and the next one was 12:30.

Mr. MENDELL. That was for antemortem inspections, yes, sir.

Mr. STUPAK. Right. But here your audit only takes place between 8:00 a.m. and noon.

Mr. MENDELL. OK.

Mr. STUPAK. So when the animals were going by for this inspection to see if you have downer cows this audit, they weren't present?

Mr. MENDELL. Who wasn't present?

Mr. STUPAK. This audit, the animal welfare audit of beef by Silliker, this audit you paid for.

Mr. MENDELL. Right.

Mr. STUPAK. The critical part of this testimony, or, I am sorry, of this hearing, is the downer cows having to move from here to there.

Mr. MENDELL. Right.

Mr. STUPAK. That occurs between 6:30 in the morning and again at 12:30 in the afternoon. According to this audit that you are relying upon to show your good practices they are only present between 8:00 and 12:00. They missed the critical phase we are talking about.

Mr. MENDELL. Is that what time those animals got moved?

Mr. STUPAK. It is right here.

Mr. MENDELL. That is what time the USDA went outside.

Mr. STUPAK. I am going off the audio of the video.

Mr. MENDELL. OK.

Mr. STUPAK. So what I am saying is if you are relying on this audit, the key times we are looking for your auditors weren't present?

Mr. MENDELL. Yes, obviously.

Mr. STUPAK. OK. And the other one didn't have times when they were present, just they were there November 13, 14.

Mr. MENDELL. It is just saying it is in that 8:00 to 12:00 period.

Mr. STUPAK. Let me ask you this question. I indicated earlier that in both 2003 and 2004 you went after, or I shouldn't say after, you contracted for the national school lunch program. And in there because of the school lunch program there is greater scrutiny of your operation, is that correct?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. So the risk of downer cows becomes more critical, correct?

Mr. MENDELL. Absolutely.

Mr. STUPAK. And the Wall Street Journal article I am reading says that the plants that slaughter animals are the major buyer of older, spent dairy cows from many dairy farms in the inland valley, is that correct?

Mr. MENDELL. That is correct.

Mr. STUPAK. Do you also buy cows from a 15-state area?

Mr. MENDELL. Fifteen?

Mr. STUPAK. Yes.

Mr. MENDELL. No. Probably six.

Mr. STUPAK. Six-state area. OK. I think that has been covered. What happened to Mr. Salas? Another worker told police Mr. Salas only came outside and he couldn't be reached for comment.

Mr. MENDELL. When this incident occurred, we suspended Pablo Salas until we reviewed all the documents that he had in place, and reinstated him to provide them all for USDA because I felt he did—he was doing his job. I wanted to make sure that all the paperwork was in order, that this gentleman did go through orientation and two training periods in a 6-week time, as well as documentation of backup for the rest of the people that worked there.

Mr. STUPAK. Are you ready for the next question?

Mr. MENDELL. Yes, sir.

Mr. STUPAK. I had asked you earlier about class 3, and I thought it was the serious adverse health. That is not true. Class 1 is adverse health. Class 2 is serious adverse health. Class 3 is likely to cause adverse health consequences—not likely to cause adverse health. I am going to put this as part of the record so we have it for the record in case any other member wishes to refer to it during their questions. Last question, these two audits, you had these audits, the two you have submitted as part of your testimony, do you know when auditors are coming, like this Silliker?

Mr. MENDELL. I personally don't but I am sure——

Mr. STUPAK. Do they make arrangements with the company to come out?

Mr. MENDELL. I am sure these audits were scheduled. Yes, I am sure they were.

Mr. STUPAK. I have no further questions for this witness. Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. Mr. Mendell, in your opening, your testimony, you testified receiving death threats, is that correct?

Mr. MENDELL. Yes, I did.

Mr. SHIMKUS. And death threats at home, folks calling at home?

Mr. MENDELL. Yes.

Mr. SHIMKUS. I just put that in the record to—I think a lot of us have been under crises modes. We have to put some stuff in perspective as far as shutting down the plant, putting a lot of people out of employment, going through the processes. Actually to some extent I am surprised and encouraged that you are here testifying today. When I was a county treasurer, I conducted the principle of management by walking around, brief familiar. Dr. Burgess kind

of talked about that a little bit. You said you walked around occasionally. What is occasionally?

Mr. MENDELL. Obviously not as much as I should but I was—my work was administrative mostly, sales, banking, collecting money, whatever. I was in the plant a lot more than I was out, outside of it.

Mr. SHIMKUS. Yes, let me just follow up. If you were not out inspecting, who was? Did you trust him to inform you of any inhumane treatment being committed outside in the pens?

Mr. MENDELL. Yes, I trusted the personnel that were out there along with the training that we had given them, yes.

Mr. SHIMKUS. Did you trust them and the other employees to alert you to any actions that would pose a threat to public health?

Mr. MENDELL. Yes.

Mr. SHIMKUS. Had anyone ever alerted you to these kind of actions before?

Mr. MENDELL. Never.

Mr. SHIMKUS. I want to follow up on this 500 cow issue. This came up in a first hearing, and the question that was posed, and we didn't have the ability to get answers, is the incentive for pushing to the 500 limit, what extraordinary actions would the employees go to to reach 500? Was there a financial incentive, and can you answer those questions? How are these folks paid? Are they paid hourly or are they paid by the process? You understand where the question——

Mr. MENDELL. Yes. I believe most of the people there are paid by the hour. The supervisors are on salary. 500 a day was the optimum number for that plant based on economics, based on weight divided into fixed expenses.

Mr. SHIMKUS. So there was no additional payment per cattle processed through a financial incentive to the employee——

Mr. MENDELL. No.

Mr. SHIMKUS [continuing]. To push product through that they may have believed was unsafe just for the financial aspect.

Mr. MENDEL. There were days we killed 493 and days we killed 510.

Mr. SHIMKUS. And the last line for me is this whole spent dairy cattle issue.

Mr. MENDELL. Yes, sir.

Mr. SHIMKUS. And it was raised also in the previous hearing, spent dairy cows or spent dairy cattle. They are at the end. And that is why they go to different processes other than others. I think by definition they are a cheaper meat because they are not beef cattle. They are spent dairy cattle. So that has additional challenges in the processing of these then healthy cattle that are going through the processes. Is that a correct assumption?

Mr. MENDELL. I think a lot more dairy cows get condemned per day than say in that steer plant, yes.

Mr. SHIMKUS. So in this business model there is a larger risk of purchasing spent dairy cattle, can I make that assumption?

Mr. MENDELL. There are more condemned. There is more of a condemn rate, yes.

Mr. SHIMKUS. That is the end of my questioning. Thank you, Mr. Chairman.

Mr. STUPAK. We have 11 minutes left on the floor, but before we continue with questions let me just—one of these documents you gave us, Westland/Hallmark Meat Company by Sean Thomas, saying that he signed or had training. It says trade secret. Do you want that in the record or not?

Mr. MENDELL. Yes.

Mr. STUPAK. OK. Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman. And I want to add my thanks, Mr. Mendell, for you coming today and giving the best and most honest answers that you could. I know that it is not an easy task. But as the consumer protection subcommittee develops our legislation around meat safety having this testimony from someone whose plant really had a terrible problem really helps us develop this legislation. Mr. Burgess asked you if you would have taken quicker action if the Humane Society would have given you the videotape at the time they gave it to the prosecutors, correct, and you said, yes, you would have taken quicker action?

Mr. MENDELL. Yes, I probably would have.

Ms. DEGETTE. And then Ms. Schakowsky asked you about the whole sequence of events with the USDA, and you stressed to Ms. Schakowsky that in your company's opinion there was really no danger to this meat, correct?

Mr. MENDELL. To the best of my knowledge, I thought there wasn't, no.

Ms. DEGETTE. Right. And so here is my question. What would you have done—you didn't recall the beef until the USDA told you to recall the beef, right?

Mr. MENDELL. Correct.

Ms. DEGETTE. And that was about 10 days, according to your testimony, after you learned about the Humane Society videotape, right?

Mr. MENDELL. Correct.

Ms. DEGETTE. So my question is if you would have learned about it right away, what is it that you would have done differently, install the cameras?

Mr. MENDELL. Yes, I would have.

Ms. DEGETTE. Would you have done anything else? Would you have recalled the meat?

Mr. MENDELL. Not—no.

Ms. DEGETTE. No, because you didn't recall the meat until 10 days after you learned about the video.

Mr. MENDELL. The first video that we received it was inhumane treatment of animals. That is what I was acting on.

Ms. DEGETTE. So what would you——

Mr. MENDELL. Till the last——

Ms. DEGETTE. So you would have tried to have more humane treatment of the animals but you wouldn't have done anything about the downed cattle?

Mr. MENDELL. I didn't know about the downed cows until later.

Ms. DEGETTE. When did you know about the downed cows?

Mr. MENDELL. That is the tapes that the Humane Society held, the ones with the downed cows.

Ms. DEGETTE. Right. But you didn't—so when you received those tapes you weren't told until 10 days later by the USDA to recall the beef, right?

Mr. MENDELL. I have never seen the downed cows going in the knocking box tapes until today.

Ms. DEGETTE [continuing]. Oh, OK.

Mr. MENDELL. So I acted on animal——

Ms. DEGETTE. So your view was that seeing those downed cows on the videotapes that you received from the Humane Society, the only concern you had was the humane treatment concern, right?

Mr. MENDELL. That was my concern, ma'am.

Ms. DEGETTE. And so really you would have never recalled this beef until you were told to by the USDA, right?

Mr. MENDELL. If I hadn't seen those videos there would have been no reason for it.

Ms. DEGETTE. But you did see the videos and you still didn't think it was anything bigger than the—and there were downed cows in those videos but you didn't think it was a problem because you didn't see on the videos that they went into the processing——

Mr. MENDELL. I reacted to the inhumane treatment of animals until——

Ms. DEGETTE. OK. You can answer my question. You thought it was an issue of inhumane treatment but you didn't think there was any kind of food risk because on the tapes you didn't see those going into the processing stream?

Mr. MENDELL. That is correct.

Ms. DEGETTE. Thank you. So, Mr. Chairman, I guess that my conclusion from this line of testimony is that we really need to—most consumers in this country think that we have mandatory recall. The FDA does not have mandatory recall authority and the USDA recall authority is very long and involved. It is not an immediate mandatory recall authority. And this is what Congresswoman DeLauro had been working in our bill because what you get is you get people who even if they see the visual evidence that there are downed cows if they don't see the actual evidence that it goes into the food stream then they have got a business incentive not to voluntarily recall that meat, and so I think two things. Number 1, if you had mandatory recall authority by the USDA and the FDA, it would be more of an incentive on business owners to make that next leap to say if I see the downed cows there marching towards the processing, I am going to assume that those downed cows may go into the food stream, and I am going to take voluntary action. And the second thing is it would give the USDA an ability to actually take mandatory recall authority when the health of our citizens is at risk. And I yield back.

Mr. STUPAK. Thank you. Mandatory recalls in the Dingell, Pallone, Stupak bill too. Jan, go ahead for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I want to ask you, Mr. Mendell, how would you describe the training program?

Mr. MENDELL. The what program?

Ms. SCHAKOWSKY. The training program.

Mr. MENDELL. I think it is—it is pretty intense.

Ms. SCHAKOWSKY. Could you elaborate?

Mr. MENDELL. I don't have it with me. I can have copies sent to you. I will gladly have copies sent to you or to the committee.

Ms. SCHAKOWSKY. Could you give us some sense of how long it is or is it hours, is it days?

Mr. MENDELL. I believe it is 50, 60 pages maybe.

Ms. SCHAKOWSKY. The manual, but the program itself, the training program that——

Mr. MENDELL. Yes. The training program itself that they go through on a monthly basis I believe is 50 to 60 pages, if I am not mistaken. It takes an hour, hour and a half probably to go through it.

Ms. SCHAKOWSKY. And you prepared to say under oath that everyone who signed a paper like this actually went through that training program?

Mr. MENDELL. Yes, ma'am.

Ms. SCHAKOWSKY. And if we were to call on your employees, some employees, do you believe that every single one of them would say that before signing this paper that they actually went through that training program?

Mr. MENDELL. It is depending on management to put them through that training program, but as far as I am concerned, yes, everyone of them has gone through.

Ms. SCHAKOWSKY. And so everyone that we might call or subpoena or whatever to come in, you feel confident that all of them would have gone through that program?

Mr. MENDELL. I feel confident that middle management has put every one of those employees through training.

Ms. SCHAKOWSKY. Now I am looking through your attachments, quality management system, the QMSC committee members, and I notice, for example, that on that committee is Pablo Salas, the plant manager, and the Humane Society person said that he spent about 15 to 20 minutes a day actually by the pens. I wanted to ask you who among those on the quality management system actually were there.

Mr. MENDELL. Was the supervisor, Daniel Agardi was his name.

Ms. SCHAKOWSKY. I don't see him on the—he is not a member of that committee or is he because I am looking at——

Mr. MENDELL. I am not certain what you are looking at but he was the pen foreman.

Ms. SCHAKOWSKY. OK. And is that person there full time?

Mr. MENDELL. Yes, ma'am.

Ms. SCHAKOWSKY. I see. So is anybody who is on the quality management system, your name is on there, Pablo Salas, Tony Cuevas, Gustavo Manzo, Martin Laguna, Henry Wong, Martin Gonzalez, Tony Gonzalez, Tony Padilla, and Steve Sayer, are any of those people who are on the quality management system committee there to observe what goes on day-to-day?

Mr. MENDELL. I am sure they interact on a daily basis or bi-daily basis or intermittently, yes.

Ms. SCHAKOWSKY. Intermittently, but are any of those people who are on that—because it says in the event of an audit the QMSC would meet to evaluate plant's conditions and practices, so one would assume that people that are assigned to that committee would have some sort of responsibility assigned to them to actually

check out conditions. Do they have as part of their job description any prescribed times or assignments to observe this?

Mr. MENDELL. I know that Steve Sayer has done the in-plant audits, which included humane handling. I know that he does it. I know that Stan Mendell does it.

Ms. SCHAKOWSKY. And so that means that he has to be on the—he has to be there to see it?

Mr. MENDELL. Well, Daniel Agardi could be off that list. I am not sure. He doesn't work there anymore.

Ms. SCHAKOWSKY. All right. Thank you. We have a vote. And I appreciate your testimony.

Mr. STUPAK. We have a minute and 30 seconds left to get to vote. We are probably going to have 2 votes. We are going to stand in recess. And, Mr. Mendell, we are going to let you go. I think there are no other questions. And we will call our second panel as soon as we come back. You are free to go. We are going to probably be 20 minutes, I would think. It depends on how many parliamentarian inquiries we have. You are free to go. We will start the second panel as soon as we get back.

[Recess.]

Mr. STUPAK. We will resume. I will now call our second panel of witnesses to come forward. On our second panel we have Danielle Lachman, Divisional Merchandise Manager of Target Corporation, Mr. Daniel Wegman, Chief Operating Officer of Wegmans Food Markets, Inc., Mr. Dennis Olson, Professor at Iowa State University's College of Agriculture and Life Sciences. As you know, it is the policy of this committee to take all testimony under oath. Please be advised that witnesses have the right under rules of the House to be advised by counsel during their testimony. It looks like we are missing Mr. Wegman. I am sure he will be here in a second. We will hold a second, then we will do the oath, and we will get going. Do any of you wish to be represented by counsel? OK. We got you in the middle, Mr. Wegman.

[Witnesses sworn.]

Mr. STUPAK. Let the witnesses reflect all the witnesses answered in the affirmative. They are now under oath, which includes the opening statement. We will begin. Let us start with Ms. Lachman, if you want to start, please. Turn your mike on there. Five minutes for an opening statement. You may wish to submit a longer statement for inclusion in the record. We look forward to your testimony. Please begin.

STATEMENT OF DANIELLE LACHMAN, DIVISIONAL MERCHANDISE MANAGER, TARGET CORPORATION

Ms. LACHMAN. Thank you. Chairman Stupak, Ranking Member Shimkus, and other members of the subcommittee, good afternoon. My name is Danielle Lachman. I am pleased to be here today on behalf of Target Corporation. I am currently a Divisional Merchandise Manager for Target's Super Target grocery store operations. I have been in my current position since September, 2007, and with Target since 2003. As a Divisional Merchandise Manager for Super Target, I oversee the produce, meat, deli, and bakery departments. The merchant teams in these departments assess available prod-

ucts, select and buy the right assortment of products, and develop a Target-brand presentation for our guests in the store.

The subcommittee has invited me here to relate Target's recent interactions on labeling with the Food Safety and Inspection Service of the USDA, as well as with suppliers of certain of Target's fresh meat products. On September 13, 2007, Target received a request letter from Chairman Dingell and Stupak seeking information regarding fresh meat products and methods employed to ensure freshness. In particular, the subcommittee sought information regarding the modified atmosphere packaging used by some of Target's fresh meat suppliers. Target responded to all of the subcommittee's questions by letter dated October 4, 2007. Target also provided documentation as requested.

In addition, on November 9, 2007, in an effort to fully address the subcommittee's concerns regarding the labeling of products employing MAP technology, Target wrote to the Administrator of FSIS seeking direction regarding how to obtain approval for additional labeling on meat products using MAP. FSIS responded to Target on January 16, 2008. In its response, FSIS indicated that it was not possible for FSIS to provide direction to Target or approval of the proposed labeling language without additional information and documentation. Much of that documentation and information is not in the possession or control of Target as a retailer. Target has had no further contact with FSIS.

In addition to working with the subcommittee and contacting FSIS, Target has also reached out to its suppliers. After receiving the FSIS letter of January 16, 2008, Target asked its primary provider, Precept, a joint venture between Cargill and Hormel, if it would include the language in Target's letter to FSIS on its packaging. Precept informed Target that it had already submitted an application with different language to FSIS, which had been approved by FSIS. Target understands that Precept will begin employing the FSIS-approved labeling as early as the end of March. We understand that the new packaging will include the following language: "Color is not an indicator of freshness. Refer to use or freeze by" and then the date.

In addition, Target understands that Precept and Hormel have been actively working with a consumer group to develop additional labeling language. We understand the joint effort is aimed at ensuring that this consumer group is supportive of any additional labeling regarding the use of MAP technology. The fresh meat products sold at Super Target comply with all applicable labeling standards. Target is committed to ensuring that all food products sold at Super Target will comply with any new labeling requirements as well. We will only buy from suppliers that provide assurances that they will comply with all applicable laws and standards. Thank you for the opportunity to discuss these issues with you. I would be pleased to answer any of your questions.

Mr. STUPAK. Thank you, Ms. Lachman. Mr. Wegman, please, your statement, please, sir.

[The prepared statement of Ms. Lachman follows:]

STATEMENT OF DANIELLE LACHMAN

Chairman Stupak, ranking Member Shimkus and other Members of the Subcommittee, Good morning. My name is Danielle Lachman. I am pleased to be here today on behalf of Target Corporation.

I am currently a Divisional Merchandise Manager for Target's SuperTarget grocery store operations. I have been in my current position since September, 2007 and with Target since 2003. As a Divisional Merchandise Manager for SuperTarget, I oversee the produce, meat, deli and bakery departments. The merchant teams in these departments assess available products, select and buy the right assortment of products, and develop a Target-brand presentation for our guests in the store.

INTERACTION WITH THE OVERSIGHT AND INVESTIGATION SUBCOMMITTEE AND FSIS

The Subcommittee has invited me here to relate Target's recent interactions on labeling with the Food Safety and Inspection Service ("FSIS") of the U.S. Department of Agriculture ("USDA") as well as with suppliers of certain of Target's fresh meat products.

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INTERACTION WITH SUPPLIERS

In addition to working with the Subcommittee, and contacting FSIS, Target has also reached out to its suppliers. After receiving the FSIS letter of January 16, 2008, Target asked its primary provider, Precept (a joint venture between Cargill and Hormel), if it would include the language in Target's letter to FSIS on it's packaging. Precept informed Target that it had already submitted an application with different language to FSIS which had been approved by FSIS.

Target understands that Precept will begin employing the FSIS-approved labeling as early as the end of March. We understand that the new packaging will include the following language, "Color is not an accurate indicator of freshness. Refer to Use or Freeze By [date]."

In addition, Target understands that Precept and Hormel have been actively working with a consumer group to develop additional labeling language. We understand the joint effort is aimed at ensuring that this consumer group is supportive of any additional labeling regarding the use of MAP technology.

CONCLUSION

The fresh meat products sold at SuperTarget comply with all applicable labeling standards. Target is committed to ensuring that all food products sold at SuperTarget will comply with any new labeling requirements as well. We will only buy from suppliers that provide assurances that they will comply with all applicable laws and standards.

Thank you for the opportunity to discuss these issues with you. I would be pleased to answer any of your questions.

STATEMENT OF DANIEL WEGMAN, CHIEF EXECUTIVE OFFICER, WEGMANS FOOD MARKETS, INC.

Mr. WEGMAN. Thank you for the opportunity.

Mr. STUPAK. Do you want to pull that up just a little closer to you, that mike?

Mr. WEGMAN. OK. Mr. Chairman, Ranking Member, and members of the committee, thank you for the opportunity to appear before you. I am Danny Wegman, and I am the CEO of Wegmans, which is a 70 store supermarket chain with stores in New York, Pennsylvania, New Jersey, Virginia, and Maryland. We are a family-owned company, founded in 1916. Wegmans is committed to providing safe and wholesome food for our customers. We see the number of people who suffer from related illness each year and we need to do better for our customers.

I am also the chairperson of the Food Marketing Institute's Food Safety Task Force. This task force was created to move food safety forward through the retail environment. It is the second time this task force has been formed. It was formed 10 years ago, first of all, and at the time the topic was E. coli and ground beef, the same topic, strangely enough. And it was back then when we as a retailer, one of our customers had a case of E. coli, and we were wondering where the E. coli came from. And they were a regular shopper. The health authorities looked in their freezer. Our ground beef was there. They had it tested for E. coli. There was no E. coli there. And nevertheless the customer had it. We don't know where he got it. We were very concerned, and we said there is no—we didn't know how to eliminate E. coli in our stores and so we said the only thing we can do is urge customers to cook ground beef to 160 degrees or risk fatal illness.

My team thought it was better than saying risk dying, so we chose fatal illness. But we did this. We are in all of our stores. We introduced thermometers to our customers. We had them in all our stores. We gave actually a type of thermometer away to all our customers who wanted the ground beef, and told them what to do with it. Interestingly, ground beef sales went up, and I think the reason for that was they knew what to do with the ground beef and could eat it safely. Even at the height of our education, however, it turned out that only less than 40 percent of our customers really truly understood what we were talking about. So we had good results but we still didn't get where we wanted to be.

In May of 2002, we introduced irradiated ground beef to our customers, and our sales got as high as between around—we averaged about 5 percent of our ground beef sales. The highest week ever would have been about 10 percent. Our retails were anywhere from 10 to 20 cents higher than normal beef, normal ground beef, and we found the program was good but we didn't quite get to the sales level that we wanted. This was in 2002. Then in 2004 our supplier went bankrupt, which was SureBeam, and that had to stop us from selling irradiated ground beef.

So finally we introduced a product in August of 2006, and we didn't quite promote it in quite the same fashion because our cost was substantially higher. We had to ship the product around because it wasn't made in the same plant where our regular ground beef was, so today's date we are selling it at about 40 cents a pound higher than our normal ground beef, and the sales are only 1 percent. We still certainly believe in it. The product is tested for E. coli prior to irradiation and the irradiation is an additional step

for safety. We have chosen a level of irradiation that kills E. coli O157:H7 and is equivalent to cooking the ground beef to 160 degrees, the recommended cooking temperature for non-irradiated, which is the same as for non-irradiated, so the irradiation is an additional step in the process.

We use the word irradiated, and we use it right now in the front of our package because we felt it was—for our go to market strategy we try and be right up front with people. We are not afraid of that. We would rather tell them that it is irradiated and why we are doing it. So I guess as we sit here today in many ways we feel that we are really not getting the support of the government that we need to pursue food safety the way it should be pursued. We feel that the regulations, some of them, are out of date, need to deal with new pathogens, need to deal with new technologies. Number 1, recognize that if irradiation is effective in eliminating pathogens from ground beef and allowing labeling that will communicate this to customers.

Number 2, USDA's caution about the cook to 160 degree message is understandable, but irradiated fresh ground beef should have different label—allow different wording or something to indicate that you have changed the process. We at one point, when we were reintroducing our ground beef started with traditional ground beef, must be cooked to 160 degrees to be sure that any illness causing bacteria that may be in the meat are killed. That isn't necessary with Wegman's irradiated fresh ground beef because dangerous micro-organisms have been killed or rendered incapable of causing illness. And we got a letter from the USDA that says FSIS advises consumers that for optimal safety all raw ground beef, including raw ground beef that has been irradiated, should be cooked to a minimum internal temperature of 160 degrees Fahrenheit. So if you take what they were telling us, the customers were right in only purchasing 1 percent of their ground beef because indeed it was a stupid test. Pay 40 cents a pound more and get nothing, and that is not what we know to be true, so that was a big concern to us.

Next, we think it is important to have a minimum level of irradiation if we are going to use this because there is a maximum but there is no minimum, and if you don't apply enough irradiation you really don't get the desired results that you are looking for. You are not eliminating E. coli. And right now there is no minimum. And then, second of all, we would like this to be designated by some type of a word whether it is pasteurized or whether it is ready to eat or whatever you want to call it, but it needs to be differentiated from just plain random irradiation. Many products are available in pasteurized and non-pasteurized forms, and it is not confusing for consumers to tell the difference with labeling.

An example of this is eggs. Pasteurized eggs are available for use in products that may not be fully cooked following the addition of egg, such as a Caesar salad or egg nog and customers are comfortable with it. Next, we are encouraging our customers to adopt healthy lifestyles by eating more fruits and vegetables, but these foods can pose a risk too. We believe that the list of products that can be irradiated should be expanded to include fruits and vegetables, as well as other ready-to-eat products. In today's world, I am

not convinced at all the interventions we make will be able to stop E. coli in all lettuce. I have an example of a lettuce grower who has been there for I don't know how many years. He is next to a farm, a dairy farm. He has been there forever. It is his family business.

Recently there was some kind of a problem with the irrigation pipes or something, and they caused E. coli in the lettuce. Now in theory this is just what you don't want done, but I am trying to think myself if I own a farm, and I have been there for years and the world is changing, are the right incentives there to get me to do the right things, and I am not sure they are. As an industry, we are going to try as hard as we can to audit our farmers and make sure that everything we can see is being done in anything the science can tell us, but I am not convinced that we may get there, and so I am not sure that we shouldn't be considering irradiation for vegetables that we are not going to—that we are not going to cook.

Mr. STUPAK. Let me have you finish up there. You are running a little bit over there.

Mr. WEGMAN. OK. I guess we would ask that we help protect customers from foodborne illness by encouraging and approving the use of technologies that reduce pathogens. That is basically what we are after. And I guess if—I would like to have the government have as much passion about keeping people safe with the food they eat as we do as retailers because when people come in our store, we have an obligation that they do get safe food, and we find that there are some things in there that the government is doing that seems to be sitting on the sidelines instead of taking an active position. So thank you very much. I appreciate the chance to share my thoughts.

[The prepared statement of Mr. Wegman follows:]

Summary

Testimony of
Daniel R. Wegman, CEO
Wegmans Food Markets, Inc.

Before the

Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce

Regarding
Regulatory Failure: Must America Live with Unsafe Food?

March 12, 2008

- We need to work cooperatively to decrease the incidence of food borne illness.
- Wegmans has successfully marketed and sold irradiated fresh ground beef since May 2002.
- In doing so, the company was able to educate its customers and employees about the benefits of irradiated fresh ground beef.
- When a minimum pathogen reduction is achieved by irradiation, the word 'pasteurization' should be used in labeling to clearly communicate the benefits of irradiation to consumers.
- The list of products approved for irradiation should be expanded to include ready-to-eat foods, especially fruits and vegetables.
- The use of technologies that reduce pathogens should be encouraged and approved.

Testimony of
Daniel R. Wegman, CEO
Wegmans Food Markets, Inc.

Before the

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Regarding
Regulatory Failure: Must America Live with Unsafe Food?

March 12, 2008

Mr. Chairman, Ranking Member, and Members of the Committee, thank you for the opportunity to appear before this Committee. My name is Danny Wegman and I am the CEO of Wegmans Food Markets, Inc. Wegmans Food Markets, Inc. is a 70-store supermarket chain with stores in New York, Pennsylvania, New Jersey, Virginia and Maryland. We are a family-owned company, founded in 1916. Wegmans is committed to providing safe and wholesome food for our customers. We see the number of people who suffer from food related illness each year and we need to do better for our customers.

I am also the chairperson of the Food Marketing Institute's (FMI) Food Safety Task Force. This task force was created to move food safety forward through the retail environment.

At Wegmans, we began with our ground beef 'Cook to 160°' program in the summer of 1998. With this program we educated our customers that ground beef needed to be cooked to 160°F for safety. We even labeled our ground beef with supplemental labels to remind our customers. We also educated our customers on the need to use a thermometer to determine the doneness of ground beef and that color was not a reliable indicator. Prior to this education effort, 12 % of those asked knew that ground beef should be cooked to 160°F. Following the campaign, 38% were aware.

In May 2002 Wegmans introduced the choice of irradiated fresh ground beef to our customers. We recognize that not all of our customers cook their ground beef 'well-done' before it's eaten. The introduction of this product was accompanied by an extensive employee and customer education campaign. We even went so far as to visit with the health departments in each of our market areas so they would be aware that this product was going to be introduced and so they would have time to familiarize themselves with the technology. We understood that customers would have questions and we wanted our employees to be prepared to answer questions, as well. The weeks before the introduction were spent educating our employees so they could talk to our customers about irradiation.

The product was introduced in a very transparent fashion. We held press conferences in each of our major market areas and included academics and public health officials to answer questions. The media helped us educate our customers. The coverage was extensive and many of the local evening news programs in each market had stories that exceeded 5 minutes in length. There were also stories in trade and national publications.

We talked to our customers about the benefits of irradiated fresh ground beef and offered in-store samples so they could try the product before purchase. The product was heavily promoted in our weekly add. The education and the sampling helped drive sales of the irradiated fresh ground beef to about 5% of total ground beef sales and even as high as 10% when the product was aggressively promoted.

Because customer trust is very important to us, we chose to include 'irradiated' on the principle display panel of the product label and in the product name. This transparency allows customers to make an informed purchase decision.

In January 2004, our irradiated fresh ground beef was discontinued following the closing of SureBeam, the irradiation provider. The product had developed a faithful following and we received communications from our customers asking that we find an alternative irradiation supplier and reintroduce the product.

We were finally able to reintroduce the product in August 2006, although we did not promote it to the same extent we did when it was launched in May 2002.

Our irradiated fresh ground beef goes through all the same in-plant interventions as our non-irradiated ground beef. This includes steam vacuums, organic acid washes, and carcass steam pasteurization. In addition, the product is tested negative for E. coli O157:H7 *prior* to irradiation, so the irradiation is an additional step for safety. We have chosen a level of irradiation that kills E. coli O157:H7 and is equivalent to cooking the ground beef to 160°F, the recommended cooking temperature for non-irradiated ground beef. The irradiation is an additional step in the process.

At present our sales are approximately 1% of our total ground beef sales. While this is lower than the 5-10% penetration previously achieved, it is increasing. There is a $.30 to $.40 per pound retail price difference between the irradiated and non-irradiated ground beef. However, the additional cost to us for irradiated ground beef is much greater. Because of our commitment to offering our customers a safer product, we made the decision to absorb some of the additional cost.

At present, other than the word 'irradiated,' the wording on our irradiated fresh ground beef is identical to that on our non-irradiated ground beef.

Wegmans proposes the following:

- Recognize that irradiation is effective in eliminating pathogens from ground beef and allow labeling that will communicate this to customers.

- USDA's caution about the 'Cook to 160°F' message is understandable, but irradiated fresh ground beef should have label differentiation, such as use of the word 'pasteurized.'
- If necessary, require a minimum level of irradiation to label a product 'pasteurized.'
- Many products are available in pasteurized and non-pasteurized forms, and it is not confusing for consumers to tell the difference with labeling. An example of this is eggs. Pasteurized eggs are available for use in products that may not be fully cooked following the addition of egg, such as a Caesar salad dressing or eggnog.
- We are encouraging our customers to adopt healthier lifestyles by eating more fruits and vegetables, but these foods can pose a risk, too. Expand the list of products that can be irradiated to include fruits and vegetables, as well as other ready-to-eat products.
- Help protect consumers from food borne illness by encouraging and approving the use of technologies that reduce pathogens.

Thank you for allowing me to present our views before this distinguished committee.

Respectfully submitted,

Daniel R. Wegman, CEO
Wegmans Food Markets, Inc.

Sadex Corporation

CERTIFICATE OF ANALYSIS

This Document Represents The Analytical Values Recorded For The Following Product(s):

PCN # 20080104
Date 27-Feb-08
SPSA CARGILL 01
Customer Name: CARGILL

	Customer Product Code	Product Name (short)	Lot Code	Units Received	Units Test/ Non compliant	Units Shipped
Item #1	1353	80/20FINE	071002250006	2	0	2
Item #2	1391	90/10FINE	071002250006	69	0	69
Item #3	1353	80/20FINE	071002250007	62	0	62
Item #4	1391	90/10FINE	071002250007	2	0	2
Item #5	0	0	0	0	0	0
Item #6	0	0	0	0	0	0
Item #7	0	0	0	0	0	0
Item #8	0	0	0	0	0	0
Item #9	0	0	0	0	0	0
Item #10	0	0	0	0	0	0
Item #11	0	0	0	0	0	0
Item #12	0	0	0	0	0	0
Item #13	0	0	0	0	0	0
Item #14	0	0	0	0	0	0
Item #15	0	0	0	0	0	0
Item #16	0	0	0	0	0	0
Item #17	0	0	0	0	0	0
Item #18	0	0	0	0	0	0
Item #19	0	0	0	0	0	0
Item #20	0	0	0	0	0	0
Item #21	0	0	0	0	0	0
Item #22	0	0	0	0	0	0

Grand Total of Cases Released> 135

Production Minimum Dose (kGy): 1.4 **Spec Minimum Dose (kGy):** 1.3

Production Maximum Dose (kGy): 2.2 **Spec Maximum Dose (kGy):** 2.2

These values demonstrate that the products recorded herein, comply with the stated requirements according to the specification listed under the above noted SPSA.

Processing Facility: 2650 Murray Street, Sioux City, IA 51111
USDA Establishment#: 21024/P21024

Signature: _____ **Date:** 2/27/08

Print Name: Matthew Flannigan

Receiving and Shipping Report

Sadex Corporation

Processing Facility: Sioux City, IA

Received From: **CARGILL** Date Received: **02/27/08** Time Received: 7:30:00

Trailer Seal Number: 343719 Trailer Number: 21095

PCN Number	SPSA Number	Product Code	Lot Code	Cases Received	Received By	Noncompliant Product	Cases Shipped	Shipped By
20080104	CARGILL 01	1353	071002250006	2	MJA		2	MJA
20080104	CARGILL 01	1391	071002250006	69	MJA		69	MJA
20080104	CARGILL 01	1353	071002250007	62	MJA		62	MJA
20080104	CARGILL 01	1391	071002250007	2	MJA		2	MJA
Total Quantity of Cases Received, Noncompliant, and/or Shipped:				135		0	135	

Product Temperature Per SOPs SC-6013.A and SC-6014.A:

Fresh: X Frozen: First Pallet Last Pallet

Received Temperature (°F): 30.8 30.8

Shipped Temperature (°F): 30.8 31.0

Trailer Inspection	Receiving	Shipping
1. Presence of blood or liquids on the floor	Y	Y
2. Presence of infestation	Y	Y
3. Presence of offensive odors	Y	Y

Shipped To: **WEGMAN'S** Date Shipped: **02/27/08** Time Shipped:

Customer PO: 9741210 Trailer Seal Number: 2488 Trailer Number: 21095

Sadex Released for Shipped By: _____ Date: 02/27/08

Carriers Signature: _____ Date: _____

Customer release: _____ Date: _____

Additional Information Noted by Sadex: By signing this document in the area designated "customer release" the named above acknowledges that all standards have been met, are in compliance and the product is ready for release into commerse.

Sadex Accounting Use Only:
Invoiced By: _____
Date: _____

This product has been processed in accordance with Sadex procedures which comply with USDA/FSIS, and FDA requirements.

Form F-5026
Rev. A, 10-May-06

CONFIDENTIAL COMMERCIAL INFORMATION

Mr. STUPAK. Thank you for coming. Professor Olson, if you would, please, sir, for your opening statement, 5 minutes, and if you have a longer statement, part of the record.

STATEMENT OF DENNIS G. OLSON, PH.D., PROFESSOR, IOWA STATE UNIVERSITY, COLLEGE OF AGRICULTURE AND LIFE SCIENCE, DEPARTMENT OF ANIMAL SCIENCE

Mr. OLSON. Thank you, Mr. Chairman. Thank you for inviting me to appear before this committee. I am Dennis Olson, Professor of Animal Science and Professor in charge of our Linear Accelerator at Iowa State University, which is the first food irradiation facility at a university in the United States. After World War II and President Eisenhower's Atoms for Peace Program, the U.S. Army developed a strong research program in food irradiation. That was in 1951. Thirteen years later in a joint Congress committee on atomic energy a statement from the Surgeon General said in summary it can be stated that foods irradiated up to absorbed doses of 5.6 Mrads, which would be equivalent to 56 kGy today with a cobalt-60 source of gamma radiation or with electrons with energies up to 10 million electron volts have been found to be wholesome, i.e., safe and nutritionally adequate. That was in 1965.

Interest in irradiation grew internationally, and a joint coordinated international program to look at the safety and wholesomeness of irradiated foods ensued. And a joint expert committee for the World Health Organization, the Food and Agriculture Organization, the Atomic Energy Agency or the International Atomic Energy Agency joint committee, and they issued a report in 1981 that said in their landmark report the committee conducted the "irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard," hence toxological testing of food so treated is no longer needed. That was that report, and it was a monumental report because shortly thereafter in 1983 the Codex Alimentarius Commission, which is the highest legal authority for international food standards, issued rules for irradiated foods that says any food up to 10 kGy could be irradiated.

And after that was issued, there are now 59 countries that have some irradiated foods that are approved for use with different maximum doses on those. The concern, however, was the 10 kGy because since 1973 we have been irradiating foods for our astronauts that have gone up to about 30 kGy, and so the question is, is a 10 kGy an actual limit? And so again a series of research projects ensued and in 1999 another joint expert committee with the World Health Organization, the FAO and IAEA, formed and their conclusion was foods that are appropriately prepared, packaged, and irradiated to high doses under proper conditions to sterilize them should be deemed safe. And after that report was issued again the Codex changed their rules and removed the 10 kGy limit. So irradiated foods are safe and in fact there are now 15 countries in the world that have no limit on any food that can be irradiated and several of that 15 group restrict no dose.

But the U.S. is not one of those. Even though there has been no indication FDA has ever disagreed with the joint expert committee reports, we still have very severe restrictions. We were in a catastrophe here in the United States in 1998 in December and then

January and February of 1999 where we had 35 million pounds of Billmar frankfurters and deli meats that were recalled, and the recall was due to 100 illnesses that occurred in 22 states resulting in 21 deaths, and with that occurrence, that catastrophe, 30 different organizations related to agriculture and food formed and submitted a petition to FDA for ready to eat foods, and essentially it would cover almost all foods in the U.S. except for seafood. That was in 1999. We are still waiting for that petition to be approved.

And we had another catastrophe in the fall of 2006 when we had spinach that was recalled where—that was in September and October of 2006, 199 illnesses in 26 states, 102 hospitalizations, and 3 deaths. And as I got contacted by the media, my question was is this a big enough catastrophe for FDA to issue their ready to eat approval, and a year-and-a-half later, I guess not. One issue I wanted to address is there has been some concern about does irradiation destroy the quality of the product, and so thanks to the courtesy of SADEX Corporation in Sioux City, Iowa, we have brought a number of products here that we have irradiated. I was there Monday and I watched that. As you inspect these, you will see we have a non-irradiated and an irradiated one. Every irradiated one will have a little label on it with my initials that I personally put on there, and I also have dosimetry sheets to indicate what doses those received. So I hope you take a chance to look at those and even open it up and taste it. The quality is excellent.

The last point I wanted to make is that we have some pillars of public health in the United States. About 100 years ago we were debating about whether cooking milk was appropriate, and a lot of debate on that. We now know that pasteurization of milk and juices is a pillar of public health in preventing illness. Likewise, when we chlorinate our water supply, we are preventing illness by that treatment and also by vaccinating for viruses for protecting our population. I believe that when we have widespread use of irradiation in our food supply, it will also be listed as a pillar of public health. Thank you, Chairman. I will be happy to answer questions you might have.

[The prepared statement of Mr. Olson follows:]

STATEMENT OF DENNIS G. OLSON

Mr. Chairman, I would like to thank the committee for inviting me to offer my views on food irradiation. My career has been devoted to this subject through teaching, research and commercial applications. In 1993, I commissioned the first electron-beam food irradiation facility at Iowa State University and developed an extensive program in food irradiation research and education in cooperation with many other universities.

Irradiation can be a powerful weapon in the nation's food safety arsenal. It destroys pathogenic bacteria without changing the nature of the treated food. The effect is similar to pasteurization, in that food is made safer, while maintaining the taste and appearance of the untreated product. Of course, the absence of heat means that, in comparison with pasteurization, irradiation can be applied to a much wider range of fresh or ready to eat foods. Food irradiation cannot make food radioactive. The equipment used for food irradiation does not have sufficient energy to cause radioactivity in any treated material, including food, regardless of the amount of irradiation absorbed.

Irradiation is not a new technology, and food irradiation is not a new topic, even in these halls. In June 1965, following more than twenty years of research by the Army, the US Army Surgeon General testified before Congress and concluded that "foods irradiated up to an absorbed dose of 5.6 Mrad (56 kGy) with a cobalt-60

source of gamma radiation or with electrons with energies up to 10 million electron volts (MeV) have been found to be wholesome, i.e. safe and nutritionally adequate."[1] The Surgeon General, in that report more than 40 years ago, concluded that irradiated food is safe regardless of the dose.[2] Since then, decades of increasingly sophisticated research have affirmed that conclusion. Now, more than forty years later, I welcome the opportunity to repeat that message. Irradiated food is safe.

In recent decades, irradiation has been increasingly adopted to sterilize medical products, and is now considered state of the art in medical sterilization. That same evolution should have occurred in food irradiation, and that it did not happen is quite literally a tragedy. The millions of pounds of contaminated ground beef, lettuce and spinach that have been recalled in the last eighteen months, and the sickness and death that accompanied those recalls, would have been prevented if those products had been irradiated.

The companies and the trade groups involved in these recalls, many of whom have testified before this Subcommittee, have all promised to do better. But they have also said, in a variety of ways, that despite their best efforts there is no "Kill Step" that will ensure their customers do not become sick in the future. Those assertions are simply not true. The pathogens responsible for these recalls, E. coli O157:H7, salmonella and Listeria monocytogenes, can be killed by proven, available and safe technology. Food irradiation is that "Kill Step."

I am convinced that food irradiation should be, and ultimately will be, broadly used in the food industry. As that occurs, food irradiation will become one of the Pillars of Public Health, along with chlorination of water, pasteurization of milk and juices, and vaccination, in the prevention of illness. I urge Congress to advance the application of irradiation in the food industry. To that end, approved uses of irradiation need to be expanded, regulatory agencies and public health professionals need to actively engage with consumers to educate them about the benefits of the technology. Labeling requirements, if needed, should be informative not alarming. Food processors need to be encouraged to adopt irradiation, or alternative food safety interventions that guarantee a comparable reduction in risk.

The first step needs to be an immediate increase in the scope of governmental approved uses for food irradiation. Of the products involved in the recent recalls, only ground beef has adequate approval from FDA and USDA. Irradiated ground beef is currently available in the marketplace, but in limited amounts. None of the major ground beef producers market an irradiated product.

With regard to leafy greens, which include spinach and bagged salads, the FDA allows irradiation for insect control and shelf-life extension, but does not allow it to be used for pathogen reduction. In order to allow irradiation for pathogen reduction in leafy greens, the FDA needs to approve both the use and the increased dose necessary for effective pathogen control in these products. That approval should have been granted years ago. In late 1999, a petition to allow irradiation for pathogen reduction in fruits and vegetables and other ready to eat foods (FAP 9M4697) was submitted to FDA. Eight years later, that petition is still pending. Two petitions submitted to FDA by USDA, its sister agency, also remain "pending" after more than eight years (FAP 0M4695 and FAP 9M4696). Yet, these petitions are being considered under the agency's "expedited" review process.

The FDA's review responsibility with regard to irradiation petitions is to evaluate safety. Safety in this context involves assessment of microbiological risk, potential toxicity and nutritional adequacy. Although it sounds complicated, after decades of research this evaluation should be a simple task. There is no longer any question about the safety of irradiated foods. In fact the kind of case-by-case review that the FDA requires has been irrelevant and unnecessary for more than a quarter century.

In 1980, the World Health Organization published a report summarizing all of the research to that date,[3] and concluded that any food, even if irradiated to a moderately high dose, would be wholesome. In other words, safe and nutritionally adequate. The same conclusion reached by the US Army Surgeon General fifteen years earlier. The WHO report further concluded that further research on the safety of food irradiation at moderately high doses was unnecessary.

In response to the WHO report, the Codex General Standard for Irradiated Food was adopted in 1983. Those standards provided that irradiation of any food up to

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[1] Radiation Processing of Foods. Hearings before the Congress of the UnitedStates, 9 and 10 June, 1965. Washington, DC, US Government Printing Office,1965, pp. 105–106.

[2] Wholesomeness of irradiated food. Report of a Joint FAO/IAEA/WHO Expert Committee. Geneva, World Health Organization, 1981 (WHO Technical ReportSeries, No. 659).

[3] A dose of 56 kGy is more than 10 times the maximum dose currently approved for fresh meat, and higher than the dose approved for sterilizing foods to be used by NASA in the space program. [21CFR 179.26(b)(8)]

an average dose of 10 kiloGray (kGy) presented no concern. The FDA did not adopt the Codex recommendations.

In 1999, the World Health Organization issued a subsequent report on high dose irradiation and concluded there is no irradiation dose where foods become unsafe.[4] In 2003, the Codex Alimentarius Commission, which is the highest international body on food standards, revised its 1983 Standard to lift all restrictions on food categories or dose limits for irradiated foods. The Codex standard does provide that doses above 10 kGy should only be used when needed to achieve a technological purpose. There are now 15 countries that permit the irradiation of any food, and several allow irradiation at any dose. The U.S. is not one of them. The limited approvals of irradiation in the U.S. has continued despite the support of the American Medical Association, American Dietetic Association, American Veterinary Medical Association, Center for Disease and Protection, Public Health Service, Council of Science and Technology, Institute of Food Technologists, National Association of State Departments of Agriculture and others recognizing the safety and benefits of food irradiation.[5]

The FDA apparently believes that the 1999 WHO report considered all of the studies the FDA considers relevant,[6] and has expressed no disagreement with the conclusions in that report. Nonetheless, FDA continues its outdated petition by petition review. Perhaps, in light of the evidence outlined above, the time has come to consider whether the classification and regulation of irradiation as a food additive should be changed.

When food processors discuss irradiation they often claim either that they have not studied its use, or have determined that it will damage the product, making it unacceptable in the marketplace. I believe the quality issue is not a real issue, but in any case it should not be a regulatory concern. The marketplace will ultimately decide if quality is compromised by irradiation. For my part, I have confidence in the capacity of the food industry to develop packaging, product configuration, processing temperature and irradiation dose to offer high quality and safe irradiated foods.

If there is a quality hurdle, it is a very low one. Several irradiated food products, and the non-irradiated controls, are available today for your evaluation. These products were purchased off the shelf, and irradiated in their retail packages without any intervention to improve quality. I believe they demonstrate that quality does not have to be sacrificed in an irradiated product.

Adoption of irradiation technology in the food industry is impeded by lack of timely and adequate FDA approvals, warning-style labeling requirements, the lack of engagement of public health officials to promote the safety of irradiated foods to consumers, and of course, the food industry's desire to avoid increased cost.

The cost of irradiation is a valid concern. In addition, there are only a few irradiation facilities in the U. S. currently capable of irradiating food in commercial volumes. The limited number of irradiation facilities can mean high transportation costs, but that is not unusual to a developing technology. Increased demand will lead to more, better located, irradiation facilities. Nonetheless, even with the current limited capacity, it should cost only cents per pound, including transportation. The offsetting benefits of irradiation are no recalls, no illnesses, no deaths and avoided litigation awards.

Mr. Chairman, thank you again for inviting me to testify on the application of this important pillar of public health technology; food irradiation. I solicit your help to get all foods approved for irradiation and to and eliminate the unwarranted warning-type label requirements. We should not accept the fact that a number of our citizens will get sick, be hospitalized or die because the government has not allowed the food industry to adopt food irradiation for all foods to prevent those catastrophes.

Dennis G. Olson, Ph. D.
Professor-in-Charge
Linear Accelerator Facility
Iowa State University

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[4] Joint FAO/IAEA/WHO Study Group on High-Dose Irradiation (Wholesomeness of Food Irradiated with Doses above 10 kGy) (1997: Geneva, Switzerland) Wholesomeness of food irradiated with doses above 10 kGy: report of a Joint FAO/IAEA/WHO Study Group—WHO technical report series: 890

[5] Food Irradiation: Available Research Indicates that Benefits Outweigh Risks. GAO Report (GAO/RCED-00-217) to the Committee on Commerce, Sub-Committee on Oversight and Investigations, U.S. House of Representatives, August, 2000.

[6] 70 FR 48057 August 16, 2005

SUMMARY POINTS

1. Food irradiation cannot make food radioactive.
2. Irradiated food is safe.
3. Food irradiation can be the "Kill Step" to prevent pathogens from causing illness.
4. When widely adopted, irradiation will be a Pillar of Public Health along with chlorination, pasteurization and vaccination in preventing illness.
5. More FDA approvals to irradiate all foods are needed immediately.
6. Quality of irradiated foods is not a regulatory concern and industry can overcome any quality issues.
7. Labeling of irradiated foods, if needed, should be informative not alarming.
8. Cost to irradiated foods is cents per pound and will lower as more facilities are built.
9. Expanded use of irradiation for food will decrease illness.

Mr. STUPAK. Yes, we are going to try to get some questions in. We are going to have two votes on the floor so let us start. Let me start with you, Professor, as you are grabbing a drink of water. You say in your testimony, and you alluded to it, but in your written testimony, page 3, the FDA apparently believed that the 1999 WHO report considered all the studies the FDA considers relevant and had expressed no disagreement with the conclusions in that report. This is on irradiation of foods, correct?

Mr. OLSON. That is correct.

Mr. STUPAK. And then you go on to say nonetheless FDA continues its outdated petition by petition review. Perhaps in view of the evidence outlined above, it is time to consider—and you said you are still waiting. What is the delay? It has been 1999. We are now 9 years later, almost 10 years later. Why aren't they ruling on the petition that you all put together?

Mr. OLSON. Well, there are some issues that came up with furans, and there had to be some research done on that and some market basket tests. But we need to have some common sense because we have found acrylamides in potato chips and French fries that we have been eating for decades and acrylamide is listed as a carcinogen. We felt furans in maybe slightly elevated levels in irradiated products that have high carbohydrate content, slight elevation.

Mr. STUPAK. Is that harmful? Would that be harmful?

Mr. OLSON. Well, in a pure form it would but the greatest content that we have in our market basket study that FDA did is in baby food, and so if anybody is going to be susceptible, it should be young children and baby foods have by far the highest amount of furans as any of the other foods that have been tested, but it is still a delay that has prevented the petition from coming forward.

Mr. STUPAK. Is it because the FDA doesn't have the science foundation to address the issue raised in the petition?

Mr. OLSON. I think they are fully capable of the science part. I have no doubt about that. What other issues has caused that from not being issued especially in light of what we have seen around the world, you know, it is——

Mr. STUPAK. Do other countries use irradiation, like the European Union and others, do they use it in their products?

Mr. OLSON. Frankly, we have an explosion of facilities being built, especially in the Southeast Asia area where we are going to

be experiencing this spring a tremendous amount of irradiated fruits, tropical fruits coming into the United States. That is the biggest area of activity that is occurring. We have a lot of shrimp that are irradiated in that area as well.

Mr. STUPAK. But your petition didn't include seafood, isn't that what you said, the WHO, World Health Organization, the petition you guys submitted on that behalf did not include seafood?

Mr. OLSON. That is correct because there were other petitions submitted that did include seafood.

Mr. STUPAK. So there are petitions pending before the FDA on seafood?

Mr. OLSON. The last one was in molluscan and shell fish which was approved in '95 or '97, I think it was.

Mr. STUPAK. Mr. Wegman, if I may, you said you began selling your irradiated ground beef when a consumer got sick. It wasn't necessarily traced back to your beef but that is how you got interested in this. And I have one of yours right here, Wegmans 9010 irradiated ground beef. Why did you feel it was important to put irradiated on the product itself?

Mr. WEGMAN. We just wanted to be very clear with our customers. We weren't trying to pull a fast one on them.

Mr. STUPAK. OK. To put irradiated on there, did you get approval from the FDA?

Mr. WEGMAN. We must have or we wouldn't have it on there, I guess. He can answer it better.

Mr. STUPAK. OK. I am sorry. I said FDA. It is USDA.

Mr. OLSON. USDA requires the label to say irradiated, generally irradiated for food safety with a symbol on that but that statement may be no larger than the ingredient statement on any package. But Wegmans took another step and put a billboard of it.

Mr. STUPAK. OK. As a retailer then, Mr. Wegman, did you have to work with the supplier to get the USDA to approve your label?

Mr. WEGMAN. I believe we do. If you need further exact yes or no, I can ask somebody behind me.

Mr. STUPAK. OK. On this committee we have had past hearings on carbon monoxide. Do you use carbon monoxide packaging for any of your beef or anything, Mr. Wegman?

Mr. WEGMAN. No, we don't.

Mr. STUPAK. Just irradiation?

Mr. WEGMAN. Yes.

Mr. STUPAK. OK. Let me go to Ms. Lachman then. Do you use—in your beef products?

Ms. LACHMAN. We use MAP package products, yes.

Mr. STUPAK. Carbon monoxide.

Ms. LACHMAN. I believe that is the tri-gas in there.

Mr. STUPAK. OK. If Wegmans can use irradiation on their packaging and it is rather pronounced, and I looked earlier before on the spinach and all that, and there is pretty good size labels on there. Why won't you just call it carbon monoxide as opposed to modified packaging or whatever?

Ms. LACHMAN. Quite honestly, we have to—we did submit the letter to FSIS. The language was not approved. We have worked with Hormel and Precept, or Precept who is our primary vendor.

Precept declined to pursue our language as they already had a label approved by FSIS for that packaging.

Mr. STUPAK. And what is that label that is approved by FSIS?

Ms. LACHMAN. One moment, and I can read it.

Mr. STUPAK. Is that the one that is in your testimony about it doesn't change the color or whatever?

Ms. LACHMAN. "Color is not an adequate indicator of freshness. Refer to use or freeze by" date.

Mr. STUPAK. And the reason why it doesn't change color because it has been treated with the carbon monoxide, right?

Ms. LACHMAN. I believe that is on the package. I am not an expert on that.

Mr. STUPAK. OK. I guess what I am trying to figure out, Wegmans have done the right thing to let the consumer know but when it comes to carbon monoxide we get all kinds of push back, and if Wegmans can do it successfully why can't we just put carbon monoxide.

Ms. LACHMAN. I am sorry. I can't speak for what Wegmans has done but we have been working with Hormel to pursue labeling.

Mr. STUPAK. But it doesn't say carbon monoxide on it? See, we still think the consumer has the ultimate right to know whatever it is. So I am going to go to Mr. Shimkus. We have a couple of votes on the floor. I know I got plenty more but go ahead.

Mr. SHIMKUS. Thank you, Mr. Chairman. I would like to go to Dr. Olson. Your testimony implies that when it comes to irradiation private industry is waiting for the FDA golden stamp of approval. If the FDA approved the use of irradiation for food in higher doses, do you think that more technological advances in this area by private industry would follow, ultimately reducing the costs to irradiate the food and resulting in a more affordable product to consumers?

Mr. OLSON. I think there are several factors involved. The red meat petition was approved, final rules, by USDA on February 23, 1999, and were first allowed February 23, 2000. Industry offered irradiated ground beef in May just a few months later, and so certainly industry is not going to invest until rules are in place. The second is that the high cost that Mr. Wegman talked about is a lot related to transportation. You make the product one place. You transport it to an irradiation facility. You transport it back to a distribution center. Then it gets to the retail store. And when we get an infrastructure in place even where you have an irradiation facility in line or in plant, then we are talking instead of that 40 cents it might be 5 cents.

Mr. SHIMKUS. Yes, I really believe in competitive market principles, and there is always a debate about when we intervene and the initial intervention is very costly but then I think the business tries to streamline it to make sure that they can bring a competitive product, you know, for the consumer because I think, Mr. Wegman, you know that you had sold previously irradiated beef but that company went out of business. It probably went out of business because it couldn't compete on cost. Do you know the reason?

Mr. WEGMAN. I apologize. I don't know the entire reason. My belief was that there were——

Mr. SHIMKUS. It is not your company so you don't have to——

Mr. WEGMAN. So I can say things about it. There were some lines of business that were never allowed to be irradiated that they couldn't run through their system and the fixed costs were very high. But we are looking to see if it would be around a dime, and that is what the folks say to us. But we got to get volume going through it. We would like permission to go after this thing and if I get thrown in jail can you at least bring me some water? Because we got to tell our customers that you can eat a good tasty, juicy hamburger if it is irradiated, otherwise, we would love to try that and see if this thing will really fly and get back to where we were or even higher.

Mr. SHIMKUS. Well, it is part of our challenge to because we have—I mean we will have individuals here that will say irradiate it? Radiation, no. And part of the hearing process is to get on the record the safety and efficacy so if and when we move a bill and we put this in that we don't hit these walls that will develop here, much like the whole question of the packaging, whether it is—and we just want clarity for the consumer so the consumer can choose. I have another question I want to make sure I ask of Mr. Olson.

Mr. Olson, in your testimony you state that there is no longer any question about the safety of irradiated foods. However, committee staff was told about scientific studies in Europe that claim that the irradiation processes with meat and some produce, in particular mangoes, result in the production of chemicals. You addressed this earlier to some extent in the carcinogens. But the question really deals with why do these studies don't hold merit in your eyes or do they?

Mr. OLSON. No, they don't for a couple of reasons. One is that Europe has spent a great deal of time trying to identify irradiated foods. Part of that mission is so that they can deny it but they want to be able to detect irradiated foods so you are looking at compounds that may have formed in the product that has not formed in non-irradiated foods, and there are a number of those that have been detected. But then you take the next step and you try and purify that, and then you try and see if there are any carcinogenic or any toxicological issues. And some have suggested in a pure form they might but you look at how do you approve any food additive in this country, and that is you go through extensive animal testing. And we did that for many, many years. There has been no food additive that has ever had such thorough animal testing done as this process.

In fact, if we look at other non-thermal technologies for processing technologies, they have never had to undergo the scruples of a food additive petition. In 1958 we have a food additive that is in fact either the cobalt or the linear accelerators the additive. And that is what has forced this whole issue of going through these great strides and any hence of any kind of things that might suggest they are wrong, delays, delays, delays the implementation. Maybe we need to think in terms of let us look at irradiation as any other process, microwaving, hydrostatic pressure pulse, electric fields, on and on and on. We got to quit doing this delaying factor and get it into the public health sector.

And the last point I wanted to make before, and that is what brought along chlorination of water, pasteurization of milk and juice, vaccinations, is strong continuous support from the public health professional. It is not the industry that brought in pasteurized milk. It wasn't the equipment manufacturers of pasteurizers that got this into the market place. It wasn't consumers demanding it. It was the public health professionals, and that is where we need to move forward with getting irradiation accepted into this market.

Mr. SHIMKUS. Thank you very much. And I think the other focus, what helps us is it has got to be science based. It has to go through the regular scientific process, and then we have to trust that and we have to lead by example to move in the direction that I think we think we both need to go. Thank you, and I yield back.

Mr. STUPAK. We have four votes on the floor. It is probably going to take us until 3:15. I am going to ask this panel to stay. I have questions about the tomatoes, the spinach, and the mushrooms there, and a number of other things that I want to ask about because I think it is very important in the education process, so if you will stay. We are in recess until 3:15.

[Recess.]

Mr. STUPAK. OK. The committee will come to order. We are going to go a second round of questions. I said I had a number of questions. And, Mr. Olson, Professor Olson, if I can start with you. On February 26, the CEO of Dole Foods testified that they tried irradiation and it fried their vegetables, and they said it just made them soggy and it just doesn't work. Comment on that because I see we have spinach. Explain what you got, you got spinach, you got mushrooms, you got tomatoes.

Mr. OLSON. Yes. We have spinach and we have lettuce. And even when we were getting irradiated ground beef in May, 2000, and past that, there was some reluctance and often quality was used as an issue of not moving forward. I know one company that we worked with almost 9 months until they had a ground beef recall. All of a sudden the quality is not an issue. So I think there is a little reluctance to move forward. They don't want to bother.

Mr. STUPAK. I think those mushrooms, can I irradiate them and can I put it too strong where I wreck the quality in the taste of the food?

Mr. OLSON. No, I don't think we have had anything deteriorated from irradiation on the table.

Mr. STUPAK. OK. The testimony was that Mr. Wegmans product, 40 cents more per pound of beef, and that is transportation cost mostly? Would that be fair?

Mr. OLSON. I would say most of it would be transportation costs.

Mr. STUPAK. Mr. Wegman.

Mr. WEGMAN. Eighty cents.

Mr. STUPAK. Eighty cents.

Mr. WEGMAN. Eighty cents.

Mr. STUPAK. It is 80 cents more?

Mr. WEGMAN. It is a little less. It is probably 60, 70 now but we can fix that.

Mr. STUPAK. But is that mostly transportation costs because you got to send it one place to another place to another place?

Mr. WEGMAN. It is combined, yes. It is the handling.

Mr. STUPAK. So if we use more irradiation of meat, vegetables, that would bring that cost down of it because other companies would get into irradiation, would it not?

Mr. OLSON. Yes.

Mr. STUPAK. Professor Olson, what is the downside other than maybe consumer conception? Is there a downside to irradiation? I understand when you irradiate something with E. coli it breaks the molecule and therefore it can't manifest in humans. Explain it to us a little bit, and what is the downside of it?

Mr. OLSON. Let me—just because you brought that one issue up— basically when we are controlling bacteria, we are damaging DNA. Now we can do that with electron beams. We can do that with X-ray. We can do it with gamma ray. We do it by fast moving electrons regardless of what source, and so they all have the same effect on that. But the downside, and I said it many times, the only downside is cost.

Mr. STUPAK. The cost of irradiating it or the extra handling that is involved because you put another step in it. It is my understanding you take that spinach right there. If Dole would send you a box of spinach you laid out on a belt, and I saw your public TV special on irradiation by Iowa State University, you put it on a belt and use that right in the bag, right?

Mr. OLSON. Correct.

Mr. STUPAK. And then at the end you just ship it back to Dole?

Mr. OLSON. That is correct.

Mr. STUPAK. So the cost then would be just that extra step you have to put in, but if we had more—it is cost basically then?

Mr. OLSON. That is right. And say if Dole had their own irradiation facility in their own plant, it is pennies.

Mr. STUPAK. Let us say Salinas Valley, where we got 21 outbreaks of E. coli in the last 10 years. Every 6 months we have a new outbreak in Salinas Valley, which is supposed to be America's salad bowl. Why wouldn't those growers then get together in that area and just irradiate the fruits and vegetables and be done with this problem we have?

Mr. OLSON. I think if we had a public health professional that is saying we need to ensure that we have a safe food supply and irradiation would be doing that, I think that would help a great deal. It is a little bit like metal detection. Every one of these bags have gone through a metal detector. Is it because we have a lot of metal? No. But occasionally we have that metal so to ensure that we don't have the consumer experience any metal in their product it goes through a metal detector, and that is the irradiation should be looked at as an insurance that we are not going to have E. coli or other pathogens in those products.

Mr. STUPAK. But what food borne illnesses could be prevented specifically besides E. coli if we used irradiation?

Mr. OLSON. salmonella, and in fact we can list a whole bunch of things like E. coli, salmonella, Yersinia, Listeria. There is a wide range of those. If we gave a product a dose that would control salmonella just like when we have process controls for heating to control salmonella, we control everything else. So that is the benchmark in terms of our ultimate control to make sure that we don't

have any of these pathogenic bacteria survive. salmonella is the most resistant to irradiation and the most resistant to heat.

Mr. STUPAK. The opponents of irradiation argue or they sort of believe that if we were to use more irradiation in fruits, vegetables, meat, it would be used as an alternative to prevent food borne illness such as sanitation. In other words, you wouldn't have to sanitize. You wouldn't have to worry about your sanitation.

Mr. OLSON. I have a great example for you.

Mr. STUPAK. OK.

Mr. OLSON. A hundred years ago when we were talking about pasteurization of milk, let us say the opponents of that said let us clean up the farms and let us go with certified rather than pasteurized milk, so a lot of attempts were made to do that. And one of the chief arguments against pasteurization is we are just going to let these dairy farms be dirtier. If you compare a dairy farm today versus a dairy farm 100 years ago, it is thousands of times more sanitary. So there is no incentive to be dirty. That is—it sounds maybe logical but there is no incentive to be dirty.

Mr. STUPAK. Ms. Lachman, I had asked you before but let me try to rephrase the question this way. I am still trying to get at why you are just not putting carbon monoxide on treated packages, why you just don't say carbon monoxide. Will Target comment to write to Precept, and I understand Precept was sort of a stumbling block here, will Target commit to write to Precept and request that carbon monoxide be added to labels on meat for sale at Target?

Ms. LACHMAN. As I understand it, for labeling we need governmental approval, and we have been working with Precept/Hormel to pursue language, and they already have language in place or they have language approved by FSIS.

Mr. STUPAK. But does it include carbon monoxide?

Ms. LACHMAN. No, it does not.

Mr. STUPAK. All right. In this committee and in our legislation, we have all been very clear, the consumer has the right to know. You can use fancy words but we like it like here, irradiation, carbon monoxide. Cargill and Hormel supplies your meat. Wouldn't you just easier call them and say, look, we want to include carbon monoxide. You are our supplier. If you don't want to do it, fine. We will go to a supplier who will provide us the food that we can put the labeling on it that says carbon monoxide. You really don't need FDA approval to put the carbon monoxide labeling on your food, do you?

Ms. LACHMAN. It is my understanding we need to have FSIS approval to put any labeling on regulated meat packaging.

Mr. STUPAK. How about just a sign in the store?

Ms. LACHMAN. I am not sure what is required to put a sign in the store.

Mr. STUPAK. Kyle, can you give me that exhibit? Here is at one of your stores for the public. We see it all the time, and I think we have it on the table there for you, our fresh meat and seafood set the standard for naturally fresh unlike other stores that may use carbon monoxide to preserve a product's color even after—never has and never will. Why don't you just put the sign? You wouldn't need to get FDA approval to put the sign up there saying

this meat may be treated with carbon monoxide or we will not use it. That is what we have asked you to do, not use carbon monoxide.

Ms. LACHMAN. I am not sure what is required to put up a statement with content that relates to regulated product but for a technical sign about a process or a specific product, we would certainly rely on our expert vendors to help craft language that would make sense for a consumer, but we will of course comply with all applicable laws.

Mr. STUPAK. OK. So basically the only way Target is going to do it then is if we have Hormel or Cargill put carbon monoxide on the packaging. You are not going to use your financial leverage to get them to do it for you?

Ms. LACHMAN. We continue to work with Hormel and have conversations about labeling. And what Hormel has told us is that they have been partnering with consumer groups to develop additional language for MAP product, and as late as when I spoke to them on Monday, I think as late as Friday they submitted additional language to FSIS, and they have worked with consumer groups.

Mr. STUPAK. They can, excuse the pun, they can work until the cows come home. It is not going to fly with this committee until they use carbon monoxide. And I would think that Target, like Wegman, would want to inform their consumers, not fancy words, not all this stuff we have seen, that modification that they want to put modified atmosphere packaging, MAP, as they call it, has been rejected many times by the committee. I would hope you would use your influence and just say carbon monoxide, we either use it or we don't. Let the consumer make their decision. Wegman did it. It certainly hasn't hurt them, and I think the consumer certainly has that opportunity to know that. Mr. Shimkus for questions.

Mr. SHIMKUS. Thank you very much, Mr. Chairman. I think the whole carbon monoxide debate is words have an impression and you have to overcome the GMO, genetically modified organisms, has been a scourge of the European community, and now we slowly, after years, the European community is now understanding the safety. We are using real science to understand GMOs. Likewise, irradiation, there have been years we don't have anything irradiated, but we have to do an educational process. And I think there is probably the same thing with the packaging issue. So I am following this debate. I am pretty new to the committee with interest, and that is just my 2 cents worth. There is this whole real science quality of the food supply and honesty in advertising, and somehow we are going to have to work through this.

Mr. Chairman, I am going to double dog dare you because I believe in leadership by example, and I know that you had Kevin actually partake in a food test of irradiated food, so I am going to ask my staff or the committee staff on our side to go down and grab those mushrooms, and we will have a taste test. Would you be up to that?

Mr. STUPAK. I am allergic to mushrooms.

Mr. SHIMKUS. I was going to do the tomatoes but I was afraid we would spray them all over the place.

Mr. STUPAK. I will do tomatoes.

Mr. SHIMKUS. You will do the who?

Mr. STUPAK. The tomatoes.

Mr. SHIMKUS. But we might spray them. He is allergic to mushrooms. Maybe that will help with our floor vote. No, we can't use this. He can't eat these. OK. We will do whatever. Dr. Olson, what do you recommend?

Mr. OLSON. Do spinach. Spinach was a big problem a year and a half ago.

Mr. SHIMKUS. And then we are going to go out to the flag pole.

Mr. WEGMAN. I don't know that I would eat spinach that is not irradiated.

Mr. SHIMKUS. That has not been irradiated? Oh, it has been irradiated for food safety. Have you done this, Dr. Olson?

Mr. OLSON. Now with these particular pages.

Mr. SHIMKUS. All right.

Mr. OLSON. The point was that since the non-irradiated ones have been sitting out here for several hours that maybe——

Mr. SHIMKUS. Come on now. We don't want qualifications. No difference. I think Popeye would approve.

Mr. OLSON. So how was the product?

Mr. SHIMKUS. Not bad. I am not an expert but I know that is how people are buying packages now. I think that is part of the problem of packaging in that manner. I had a friend call me unexpectedly, going to drop by, a college buddy, so I run to the store. The thing that I can do is put steaks on the grill. I can get a package of salad and zap some potatoes. And that is a quick meal but that salad is all in a bag. It makes it easy. I do this for two reasons. We are moving from meat to vegetables, and that is why I followed up on the taste test, which is fine by me.

Mr. Wegman, the selling of vegetable products, the cost of vegetable products, the consumer debate, what are your comments?

Mr. WEGMAN. Let me start with the cost. I think that we have got a long journey but I think we should get started on the journey. As far as I know, to irradiate today costs $25 million. We wanted to do that. We wanted to do our own meat plant and put irradiated ground beef in it which is too expensive for us to do it. We went with Cargill. So I think it is going to be a while before it gets down to that incremental dime whether it is ground beef, whether it is vegetables or lettuces. I think we need to be realistic about it.

Mr. SHIMKUS. Can I follow up on that? So we want to protect business. We don't want to drive folks. We want to do things safe. So in movement to this, if we are going to move in this direction how do we do that without affecting real cost?

Mr. WEGMAN. What I think we need is simply to take the barriers away. Let us figure out the economics. I mean we can do that with Sadeck and Cargill.

Mr. SHIMKUS. But if we do a certain date like, say, 6 months you can't do it. We can't turn. We don't have the equipment, we don't have the machines. The big entities will be buying forward so the small entities will be disenfranchised. So there has to be a process by which we move this through our economy and our food system in a gradual process so that we don't pick winners and losers by this process.

Mr. WEGMAN. I think we accomplish it by taking away the barriers. Let us do it on produce. Let us take away if we want to talk about rare ground beef and being able to eat it. I mean we are going to do it this summer. We are going to find a way that is legal, and we are going to do it. We want to get this moving. I think that is—you had another question too about——

Mr. STUPAK. But let me follow up on that though. But as chairperson of the Food Marketing Institute you said, right, Food Marketing Institute safety task force, are you moving toward some kind of rules or regulations you would recommend to the Congress as we move this food safety legislation for irradiation? Is your task force doing something along those lines that could give us some insight?

Mr. WEGMAN. At the moment, no. And what we are working on, frankly, is trying to get the growers to adhere to an audit process that we think takes them to a higher level without irradiation.

Mr. STUPAK. Sure, but the last recall we had in '06 was a microorganism. E. coli was found there. You can't just clean it up by washing it and all that. You almost need something like irradiation. I think E. coli has developed strains where now you need more science as opposed to just the old 100-year process that we have done in the past.

Mr. WEGMAN. That is my belief, and I think there are some things we can do but that is my belief.

Mr. STUPAK. Mr. Shimkus, did you have some more? Thanks for the gourmet lunch.

Mr. SHIMKUS. No, but I would just say that you may want to double dog dare Mr. Whitfield because I don't think he has partaken.

Mr. STUPAK. You are allergic to spinach, but it is your time for questions.

Mr. WHITFIELD. I want to thank the panel. I actually have just one question, Dr. Olson. Will your irradiation kill prions in BSE or mad cow disease?

Mr. OLSON. No. Prions are mineralized protein. They are not DNA or RNA and so we cannot destroy those. They are just too small.

Mr. WHITFIELD. OK. But does that present a safety issue?

Mr. OLSON. Well, there are other mechanisms are in place, the rule on feed bans, the downer cow issue, the symptoms, the sampling programs, all those to detect and actually prevent is almost a public health issue again. We are going to prevent that problem, not try and intervene or solve the problem by treatment.

Mr. WHITFIELD. That is all the questions I have.

Mr. STUPAK. No further questions of this panel. We will excuse you, and thank you again for your testimony and your products and your lunch. Professor Olson, let me congratulate you. On Monday we actually put in the 150th anniversary of the founding of Iowa State on the first land grant colleges. Of course, the first one was Michigan State University but Iowa State was right there too. We had that vote on Monday. We were just talking about it when you came up. Yes, Mr. Wegman.

Mr. WEGMAN. Chairman Stupak, could I thank you and your committee for your work, please? This is very important to us. It

is our life. And we are very appreciative that you are putting this effort into it. Thank you.

Mr. STUPAK. Thank you, but as the task force I would encourage you guys to develop something that we can look at, your task force on food safety with the food, that group you head up, OK? We are real interested in that. And when I mention Salinas Valley it makes sense. Every 6 months we are having an E. coli recall. Why can't we put irradiation right there where it is all being processed? It just makes sense to me. And I ask the FDA all the time do you do a epidemiology study on what is going on there. Oh, it might be the cow farm down there. Well, let us solve it. One way you can solve it is irradiation, it sounds like.

Mr. WEGMAN. And I just wanted to add one more statement, and that is if we are going to deal with raw product there is almost no kill step except for irradiation, and so I think that we need to zero in on this as a public health issue where we can have a kill step without changing the nature of the product.

Mr. STUPAK. Thank you. And thank you again, everyone on this panel. I would now like to call up our third panel of witnesses to come forward. On our third panel, we have Dr. Stephen Sundlof, Director of FDA's Center for Food Safety and Applied Nutrition, and Dr. Richard Raymond, Undersecretary for Food Safety at USDA's Food Safety and Inspection Service, FSIS. Gentleman, it is the policy of this subcommittee to take all testimony under oath. Please be advised that witnesses have the right under rules of the House to be advised by counsel during their testimony. Do any of you wish to be represented by counsel? Mr. Raymond, Mr. Sundlof? OK.

[Witnesses sworn.]

Mr. STUPAK. Thank you, and witnesses are under oath. Dr. Sundlof, do you want to start with your opening, please, sir?

STATEMENT OF STEPHEN F. SUNDLOF, D.V.M., PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Dr. SUNDLOF. Thank you, Mr. Chairman and members of the subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Thank you for the opportunity to discuss the agency's efforts to enhance food safety. I am pleased to be here today with my colleague from USDA, Dr. Raymond.

Food can become contaminated at many steps along the path from farm to fork. In recent years, FDA has done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies.

The outbreaks in the last year and a half have underscored the need to develop multi-disciplinary and integrated product safety strategies. To address these challenges, last November FDA released the Food Protection Plan, which provides a framework to identify potential hazards and counter them before they can do harm. Also at that time, Health and Human Services Secretary Mi-

chael O. Leavitt presented to the President an Action Plan for Import Safety. Together these plans provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world.

The plans encompass three core elements: prevention, intervention, and response. The prevention element means promoting increased corporate responsibility so that food problems do not occur in the first place. The intervention element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The response element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency.

We are working with all of our food safety partners to achieve the food safety enhancements identified by these plans. To implement the Food Protection Plan, FDA is requesting 10 new authorities, and we seek the assistance of members of this subcommittee to help obtain passage of these.

For example, FDA is requesting the authority to require entities in the food supply chain to implement measures solely intended to protect against intentional adulteration of food by terrorists or criminals. We also request explicit authority to issue regulations requiring preventive food safety controls for high-risk foods. Such authority would strengthen FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point, or HACCP, or equivalent processes to reduce foodborne illness from these foods.

Some of the other legislative proposals include: authorizing FDA to accredit and use highly qualified, independent third parties to evaluate compliance for voluntary inspections; allowing the FDA to move the inspection of high-risk products of concern upstream by requiring the exporting countries' regulatory authority or third party inspector to certify each shipment for compliance with FDA standards prior to shipment; giving FDA authority to issue mandatory recalls if a voluntary recall is not effective, authorizing the FDA to refuse admission of imported food if inspection access has been delayed, limited, or denied.

In addition to numerous other outreach activities underway to engage our stakeholders in implementing the Food Protection Plan, FDA is planning to host a meeting in August with regulatory, epidemiology, and laboratory officials from the Departments of Health and Agriculture from all 50 states. This will provide a forum for local, state, and federal partners to exchange information and ideas about implementing the plan and enhancing domestic food safety.

To address the ongoing issue of safety of lettuce and leafy greens, FDA is continuing to work with officials in California and with industry to assess the prevalence of factors in and near the field environment which may contribute to the potential contamination of leafy greens with E. coli O157:H7, and the extent to which good agricultural practices and other preventive controls are being implemented.

In the fall of 2007, in cooperation with industry, state and local governments, and academia, FDA conducted assessments on farms. By identifying practices and conditions that can lead to product contamination, FDA and its food safety partners hope to improve guidance and policies intended to minimize the potential for future

disease outbreaks, as well as to ascertain future food safety research, education, and outreach needs.

As part of its Tomato Safety Initiative, FDA is continuing its collaboration with the state health and agricultural officials from Florida and Virginia, the produce industry, and several universities to prevent foodborne illnesses associated with tomatoes from those states. FDA is leading the effort to conduct assessment of the factors most likely to be associated with the previous salmonella contamination. Last summer, assessments were conducted in the field and at packers. Similar assessments will be conducted in Florida this spring. Information from these assessments will help inform appropriate preventive measures.

With regard to imported food safety, in December, the Department of Health and Human Services and the People's Republic of China signed a Memorandum of Agreement or MOA to enhance the safety of food and animal feed products exported from China to the United States. The MOA establishes a bilateral mechanism to provide greater information to ensure that products from China meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and certification requirements, greater information sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress.

FDA has also made a commitment to station inspectors and other agency representatives in China to increase our ability to carry out foreign inspections and to facilitate cooperation between FDA and its counterpart regulatory authorities. FDA is considering similar endeavors in other countries. Last month FDA briefed representatives from 48 embassies to discuss both plans and to engage their assistance in implementation.

Mr. Chairman, thank you for the opportunity to discuss FDA's food safety activities. We look forward to working with you to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Import Safety Action Plan. And I would be happy to answer any questions.

[The prepared statement of Mr. Sundlof follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Rockville MD 20857

STATEMENT OF

STEPHEN F. SUNDLOF, D.V.M., PH.D.

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FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

U.S. HOUSE OF REPRESENTATIVES

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INTRODUCTION

Good morning, Chairman Stupak and Members of the Subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss the Agency's efforts to enhance food safety. I am pleased to be here today with my colleague, Dr. Richard Raymond of the U.S. Department of Agriculture (USDA).

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission--to protect and promote public health.

Food can become contaminated at many different steps along the path from farm to fork – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, and tribal food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain. This cooperation has resulted in greater awareness of potential

vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies. The outbreaks in the last year and a half underscored the need to develop multidisciplinary and integrated product safety strategies.

To address these challenges, last November, FDA released a Food Protection Plan which provides a framework to identify potential hazards and counter them before they can do harm. Also at that time, HHS Secretary Michael O. Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. To achieve the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, and tribal governments; industry; academia; consumers; and Congress. We seek the assistance of the Members of this Subcommittee to help obtain passage of the necessary legislative authorities.

I would now like to describe some of the highlights of the Food Protection Plan and the food-related items of the Action Plan for Import Safety and some recent food safety and food defense activities.

FOOD PROTECTION PLAN

The Plan builds in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach, within the Food Protection Plan, encompasses three core elements: prevention, intervention and response.

The *prevention* element means promoting increased corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency.

While American consumers enjoy one of the safest food supplies in the world, growing challenges require a new approach to food protection at FDA--an increased emphasis on prevention. Outbreaks in the last year and a half that were linked to fresh produce, peanut butter, and pet foods show how FDA responds quickly to contain food safety problems. While this level of response needs to be maintained and even enhanced, there is also a need to focus more on building safety into products right from the start to meet the challenges of today.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses, (2) identify food vulnerabilities and assess risk, and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

First, to promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, importers, and other critical components of the food supply chain. FDA will continue to work with industry, state and local governments to further develop the tools and science needed to identify vulnerabilities and determine the most effective approaches. For example, in December 2007, FDA released self-assessment tools to minimize the risk of intentional contamination of food and cosmetics. The tools enable industry to get a quick and detailed assessment of the security measures they have in place and to identify areas in which improvements are needed.

FDA is requesting new authorities to accomplish this first goal. The Agency is requesting the authority to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals. FDA would use

this authority to issue regulations to require companies to implement practical food defense measures at specific points in the food supply chain. This authority would apply to food in bulk or batch form, prior to being packaged.

FDA is also seeking explicit authority to issue regulations requiring preventive food safety controls for high-risk foods. Such authority would strengthen FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from these foods.

Second, to identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. The components of such an approach include but are not limited to: risk management, risk analysis, risk assessment, risk-based workplanning, and risk communication. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health. By analyzing data collected throughout the food product life cycle, we are better able to detect risks posed by food products. We are also better able to recognize key junctures where timely intervention can reduce or avoid those risks.

Working with the Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will be providing CDC with two epidemiologists to work on attribution using CDC's electronic foodborne disease outbreak reporting system data. FDA will also continue to work with the Department of Homeland Security on identifying emerging risks and developing rankings so that we can more effectively allocate our available resources to manage these risks.

Third, in order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about sources, spread and prevention of contamination. We will also develop new mitigation tools and implement appropriate risk management strategies. Building on risk assessments, FDA will initiate focused research to enhance our understanding of sources of contamination, modes of spreading, and how best to prevent contamination. This information will inform FDA's efforts to promote increased corporate responsibility to implement effective preventive steps.

Focusing on higher risk foods, FDA will continue to conduct research and leverage relationships with outside organizations. FDA will also research, evaluate, and develop new methods to detect contaminants in foods, and seek to facilitate new technologies that enhance food safety. For example, FDA is doing extensive research on molecular virology, microbial genetics, and the detection, characterization, and behavior of foodborne pathogens. These efforts are necessary to develop risk assessment models

for pathogens such as *E. coli* O157:H7, *Listeria monocytogenes,* and *Clostridium botulinum.* FDA's food safety research program includes an intramural program, extramural program, interagency cooperation, and consortia with industry and/or academia.

To enhance the safety of lettuce and leafy greens, FDA is continuing to work with officials in California and with industry to assess the prevalence of factors in and near the field environment which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which Good Agricultural Practices and other preventive controls are being implemented. In the fall of 2007, in cooperation with industry, state and local governments, and academia, FDA conducted assessments on farms. By identifying practices and conditions that can lead to product contamination, FDA and its food safety partners hope to improve guidance and policies intended to minimize the potential for future disease outbreaks, as well as to ascertain future produce-safety research, education, and outreach needs. As part of the multi-year Leafy Greens Safety Initiative, FDA has worked with industry, academia, and other government agencies including public health officials to identify and prioritize research; worked with industry to secure industry funding for research and to develop commodity-specific guidance documents; and worked with USDA to make resources available for priority research and to conduct studies examining both the current challenges and future solutions.

FDA is also continuing its collaboration with state health and agriculture officials from

Florida and Virginia, the produce industry, and several universities to prevent foodborne illness associated with tomatoes from those states. As part of its Tomato Safety Initiative, FDA is leading the effort to conduct assessments of the factors (including irrigation water, drought and flooding events, the proximity of animals to growing fields, and post-harvest water use) that are most likely to have been associated with previous *Salmonella* contamination. Last summer, assessments were conducted in the field and at packers. Similar assessments will be conducted in Florida this spring to coincide with the tomato production and harvesting season. Information from these assessments will help inform appropriate preventive measures.

Last October, the Food and Agriculture Organization/World Health Organization conducted an expert panel that concluded that the safety of leafy greens and herbs merits attention by the Codex Committee on Food Hygiene (CCFH). FDA has assembled a group of experts and is currently drafting a leafy greens and herbs annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables to address in more detail specific controls to prevent the presence and growth of pathogens in these foods.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance, and improve the detection of food

system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense. Therefore, legislation to authorize FDA to accredit and use highly qualified independent third parties to evaluate compliance with FDA requirements would be an effective way to further meet the heightened inspection demand. FDA would not be bound by these third-party inspections in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by FDA when setting inspection and surveillance priorities.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving its ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing agreements with key foreign countries.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority. That authority (or an FDA-recognized third party inspector) would certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment. FDA would apply this requirement for imported products that have been shown to pose a

threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with FDA's.

In addition, while FDA currently has the authority to pursue an inspection warrant or initiate criminal investigations if it is denied access to inspect facilities here in the U.S., our ability to enforce the inspection provisions for overseas sites is very limited. In particular, although FDA can refuse admission of food that appears to be adulterated or misbranded, FDA cannot refuse admission of food if FDA is hampered in making this determination because its efforts to conduct a foreign inspection were unduly delayed, limited or denied at a facility where the product was manufactured, processed, packed or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable FDA to keep possibly unsafe food from entering U.S. markets.

FDA can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to "map" or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for emerging food protection problems.

The recent pet food recalls showed us that we need to also increase our efforts on animal food and feed, as well as human food. To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA is working with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to identify problems with the pet food supply and alert veterinarians and others.

FDA also is developing a modernized risk-based Animal Feed Safety System (AFSS) that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals. With state assistance, FDA is developing an AFSS framework document that identifies the current major processes, guidance, regulations and policy documents that address feed safety and the documents that should be developed to make the Agency's feed safety program comprehensive and risk-based. We expect to hold a public meeting on the AFSS risk model in the next few months.

To implement a requirement in the Food and Drug Administration Amendments Act of 2007, FDA is developing ingredient, processing, and updated labeling standards for pet food. We are also developing ingredient and processing standards for animal feed.

Response

During the past year and a half, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods.

While FDA's response to these outbreaks was swift and effective, there is always a need to respond faster and communicate more effectively with consumers and other partners. During emergencies, important messages must be communicated clearly and through multiple forms of media to consumers and retailers. FDA will enhance its risk communication program through aggressive, targeted campaigns that disseminate clear and effective messages and provide regular updates to help get contaminated products off the retail shelf and out of homes more quickly. FDA has sought advice from the recently formed Risk Communication Advisory Committee to obtain expert advice in the field of risk communications.

To improve our immediate response, FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track-and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. Although FDA has the authority to pursue seizure of adulterated or misbranded food through a civil judicial action, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct an effective recall. In such situations, public health would be best

protected if FDA has the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is seeking a modification to our records access authority that would give FDA more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health. The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated *and* presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related*

articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario.

We are moving forward to implement the Food Protection Plan and are working with other Federal agencies; state, local, tribal, and foreign governments; as well as with industry to develop the food science and tools necessary to better understand the current risks of the food supply, and develop new detection technologies and improved response systems to rapidly react to food safety threats.

To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA is planning to host a meeting in August with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 states. We also have numerous other outreach activities underway to engage our stakeholders in implementing the Food Protection Plan.

ACTION PLAN FOR IMPORT SAFETY

On November 6, 2007, Secretary Leavitt presented the Action Plan for Import Safety (Action Plan) to the President. This Action Plan shares with the Food Protection Plan the organizing principles of prevention, intervention and response. The general thrust of the Action Plan is to broaden our focus from examining products as they enter the U.S. to monitoring imported products throughout their life cycle from production to consumption, paying particular attention to the critical points of risk along the way where safety can be compromised and safety standards are most needed. It recommends many of the legislative authorities identified in the Food Protection Plan.

It also recommends that FDA examine food safety control systems of other countries to provide the Agency with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention, and response activities.

Consistent with the goals of the Action Plan, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of food and animal feed products exported from China to the U.S. The MOA establishes a bilateral mechanism to provide greater information to ensure products from China meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and

certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress.

FDA has also made a commitment to station inspectors and other Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries.

Last month, FDA briefed 62 representatives from 48 embassies to discuss both plans and engage their assistance with implementation.

CONCLUSION

Together, the Food Protection Plan and the Import Safety Action Plan provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We look forward to working with the Members of this Committee and the entire Congress to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Import Safety Action Plan. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.

Mr. STUPAK. Thank you. Mr. Raymond, your opening statement, please, sir.

STATEMENT OF RICHARD A. RAYMOND, M.D., UNDER SECRETARY FOR FOOD SAFETY, UNITED STATES DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE

Dr. RAYMOND. Mr. Chairman and members of the subcommittee, I am pleased to appear before you today to address the ongoing investigation of the Hallmark/Westland Meat Packing Company in Chino, California, among other issues that you have. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory, disabled cattle in that facility. As soon as we learned of the problems at Hallmark/Westland we took immediate steps to determine if the allegations made public by the Humane Society of the United States were accurate. The USDA's Office of the Inspector General is leading this investigation with support from FSIS and AMS.

Pending the conclusion of the investigation, the Secretary announced 2 weeks ago that we will be implementing a series of interim actions to verify and thoroughly analyze humane handling activities in all federally inspected establishments. We have already begun those actions. The Federal government has an interlocking system of controls to protect against BSE. The FDA's ruminant-to-ruminant feed ban which began in 1997 is the most significant step that the Federal government has taken to protect animal health. The single most important thing we can do to protect human health regarding BSE exposure is the removal from the food supply of specified risk materials or SRMs. These are tissues that, according to the available scientific evidence, could be effective in a cow with BSE.

According to the Harvard risk assessment, the SRM removal process alone reduces the risk of BSE exposure to consumers by 99 percent. After the first case of BSE was detected in the United States, the USDA conducted an enhanced BSE surveillance testing program for 2 years. During this time, only two animals were detected with BSE and that is out of over 759,000 high risk animals that we have tested to date. It is important to note that both of those animals were born prior to the initiation of the FDA's feed ban and neither of those animals did enter the food supply. The rule prohibiting non-ambulatory cattle from entering into the food supply is simply one of the multiple measures that we have in place. Because of these measures, we can be confident of the safety of our beef supply in regards to BSE exposure.

I would like now to briefly highlight our efforts to further protect human health from foodborne pathogens. Based on the Centers for Disease Control and Prevention's annual food net data report, we are making some progress towards meeting the Healthy People 2010 goal regarding the incidents of foodborne illness, but we do know that we still have work to do to further reduce foodborne illness in foods that we regulate. Following an increase in positive product test results and recalls of E. coli O157:H7, which I will just refer to E. coli from now on. Last fall, the Food Safety and Inspection Service announced several new ongoing actions to protect the public against the risk of E. coli including expanded testing.

It is important to keep things in perspective, however. Although we ended 2007 with 21 recalls due to E. coli and the percentage of FSIS E. coli positive samples for 2007, which was 0.23 percent, is still well below the percentage of positives as recently as 2001 when it was 0.87 percent. FSIS also collects and analyzes samples of raw meat and poultry product for salmonella. Because of 4 years of steady increase in salmonella positive product testing results, the FSIS announced an 11-point risk-based strategy for salmonella reduction in raw products in February, 2006. We can easily see the positive result of this risk-based strategy. The percentage of plants that fall into the best performing category has increased dramatically from 35 percent when we announced the plan to 74 percent at the end of 2007.

On March 28, 2008, the agency will begin posting on its Web site completed verification test results from establishments with salmonella rates in other categories beginning with young chicken slaughter establishments. Very briefly, we have gone from approximately 17 percent of chicken carcasses testing policy for salmonella to about 7.4 percent in these 2 years. At FSIS we rely on the efforts of our partners to help us in our mission to protect the public's health. FSIS works in collaboration with the sister agencies on multi-jurisdictional food safety issues, whether those agencies are Federal, state or local entities. Two examples of these successes of the foodborne disease active surveillance network are Food Net and Pulse Net.

These two systems allow agencies to collaborate and bring their specialized knowledge together to better protect public health. I know another area of interest for this subcommittee is how the agency ensures the safety of imports. FSIS uses a comprehensive system to ensure that imported meat, poultry, and processed egg products are safe and secure. Our three-part system includes a thorough analysis of each country's food laws and inspection systems to determine initial equivalence before they can ever export. We do on site audits of each country's food safety system to verify the system is implemented in accordance with what is in writing and then to ensure that equivalence is maintained on an annual basis, and our port of entry inspection on all FSIS-regulated meat, poultry, and processed egg products coming into the United States with very few exceptions.

Before I conclude, if I might, I have 20 seconds left, I want to try to clarify something I heard earlier today regarding the USDA's recall classifications. I am not sure it still was entered in exactly correct so I am just going to read for you. A class 1, this is a health hazard situation where there is a reasonable probability that the use of the product will cause serious adverse health consequences or death. Class 2 is the health hazard situation where there is a remote probability of adverse health consequences from the use of the product, and class 3, this is a situation where the use of the product will not cause adverse health consequences.

So in conclusion, I will just stay that FSIS remains committed to improving its approach to inspection, to focus on public health and risk. And as a medical physician and a public health professional, I believe that what all of us here with a stake in food safety must accomplish is further protecting the people, especially those

most vulnerable to a foodborne illness which includes the very young, the elderly, the immune compromised, and pregnant women. Again, thank you for the opportunity to be before you and the committee today, and along with Dr. Sundlof, I am happy to try to respond to your questions.

[The prepared statement of Mr. Raymond follows:]

STATEMENT OF DR. RICHARD RAYMOND

Mr. Chairman and Members of the Committee, thank you for inviting me to appear before you today to address the ongoing investigation of the Hallmark/Westland Meat Packing Company (Hallmark/Westland) in Chino, California, and other related issues. I want to assure you that I am deeply concerned about the inhumane handling of non-ambulatory disabled cattle in that facility.

I am Dr. Richard Raymond, Under Secretary for Food Safety at USDA. While there are a number of agencies at the Department working together on this matter, the Agency for which I have responsibility is the Food Safety and Inspection Service (FSIS). FSIS is the public health regulatory agency responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry, and processed egg products prepared for distribution in commerce for use as human food. FSIS also enforces the Humane Methods of Slaughter Act, which requires that all livestock at federally inspected establishments be handled and slaughtered in a humane way.

As soon as the Humane Society's video was released on January 30, Secretary Schafer called for an investigation into the matter. USDA's Office of the Inspector General (OIG) is leading that investigation, with support from FSIS and the Agricultural Marketing Service (AMS). As the Secretary announced last week, pending the conclusion of the investigation, we are implementing a series of interim actions to verify and thoroughly analyze humane handling activities in federally inspected establishments.

I remain confident in the safety of the U.S. food supply. To help ensure its safety, we take a number of steps to prevent food-borne illness. FSIS employs over 9,000 personnel, including 7,800 full-time in-plant and other front-line personnel protecting the public health in approximately 6,200 federally-inspected establishments nationwide. FSIS personnel must be continuously present for slaughter operations and must inspect processing plants at least once per shift per day. Under the FSIS verification sampling program, FSIS samples meat, poultry, and processed egg products and analyzes them for the presence of microbial pathogens. In addition to its targeted sampling for Listeria monocytogenes in ready-to-eat products, the Agency has paid particular attention to E. coli O157:H7 in raw ground beef through the initiative announced last fall and salmonella in raw meat and poultry products through the ongoing salmonella improvement plan. To protect against bovine spongiform encephalopathy (BSE), the federal government also has an interlocking system of safeguards, which I will describe in more detail later.

INITIAL USDA ACTIONS

As soon as we learned of the problems at Hallmark/Westland, USDA took immediate steps to determine if the allegations made public by the Humane Society of the United States (HSUS) were accurate.

On February 1, 2008, Hallmark/Westland voluntarily stopped slaughter operations. As a result of FSIS findings, FSIS suspended inspection at the plant on February 4, 2008. This action was based on FSIS findings that the establishment failed to prevent the inhumane handling of animals at the facility, as required by FSIS regulations and the Humane Methods of Slaughter Act.

This suspension of inspection will remain in effect, and Hallmark/Westland will be unable to operate, until corrective actions are submitted in writing and verified through a full review by FSIS. This verification process will ensure that all animals will be handled humanely and none will be allowed to proceed to slaughter until Hallmark/Westland complies fully with FSIS regulations.

Evidence from the ongoing investigation demonstrates that, over the past 2 years, this plant did not always notify the FSIS public health veterinarian when cattle became non-ambulatory after passing ante-mortem (prior to slaughter) inspection, as is required by FSIS regulations. It is important to note that certain cattle, while

ambulatory when they pass ante-mortem inspection, may later become non-ambulatory from an acute injury or another circumstance. If such a situation occurs, FSIS regulations require the public health veterinarian to inspect the animal again and determine that the animal did indeed suffer from an acute injury before the animal is permitted to go to slaughter. This failure by Hallmark/Westland led to the company's February 17, 2008, voluntary recall of 143 million pounds of fresh and frozen beef products produced at the establishment since February 1, 2006.

While it is extremely unlikely that these meat products pose a risk to human health, the recall action was deemed necessary because the establishment did not comply with FSIS regulations. The recall was designated Class II because the probability is remote that the recalled beef products would cause adverse health effects if consumed. This recall designation is in contrast to a Class I recall, which is a higher-risk health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

SAFEGUARDS AGAINST BSE

I am aware that this situation has raised questions about the risk of BSE. I would like to take this opportunity to give you a brief summary of the safeguards against BSE that we have in place to protect our food supply.

Since the discovery of the first case of BSE in Great Britain in 1986, we have learned a tremendous amount about this disease. That knowledge has greatly informed USDA's regulatory systems and response efforts. It has also given us the opportunity to examine our own cattle herd, which is why we know that the risk of BSE in the United States is extremely low.

As noted earlier, the federal government's interlocking system of controls to protect the food supply from BSE includes a ban on non-ambulatory disabled cattle. But that is simply one of the multiple measures in place.

We have learned that the single most important thing we can do to protect human health regarding BSE is the removal from the food supply of specified risk materials (SRMs)—those tissues that, according to the available scientific evidence, could be infective in a cow with BSE. FSIS requires that all SRMs, including the brain and spinal cord, are removed from carcasses so that they do not enter the food supply. Slaughter facilities cannot operate their slaughter operations without the continuous presence of FSIS inspection personnel to ensure safe and wholesome product, including the removal and segregation of SRMs. According to the 2005 Harvard Risk Assessment, SRM removal alone reduces the potential exposure to consumers of BSE by ninety-nine percent. FSIS line inspectors are stationed at key points along the production line where they are able to directly observe certain SRM removal activities. Other off-line inspection personnel verify additional plant SRM removal, segregation and disposal. Moreover, FDA bans SRMs in FDA-regulated human foods (and cosmetics).

Likewise, another significant step we have taken to prevent the spread of BSE and bring about its eradication in the animal population is the ruminant feed ban. In 1997, the FDA implemented a mandatory feed ban that prohibits feeding most mammalian protein to ruminants, including cattle. The feed ban is a vital measure to prevent the transmission of BSE to cattle.

Another step is BSE testing, which is best used as a surveillance tool. By testing high-risk animals, including those that show possible clinical signs of the disease, we can document the effectiveness of our security measures.

USDA's Animal and Plant Health Inspection Service (APHIS) has conducted targeted BSE surveillance testing since 1990, including an enhanced surveillance effort that was initiated after a cow tested positive for the disease in December 2003. The goal of the enhanced effort, which began in June 2004, was to test as many animals in the targeted population as possible over a 24-month period. This intensive effort detected only two additional animals with the disease, out of over 759,000 animals tested. Both of those animals were born prior to initiation of the FDA feed ban and neither entered the food supply. This testing confirms an extremely low prevalence of the disease in the United States.

The enhanced surveillance program provided sufficient data to allow USDA to more accurately estimate the prevalence or level of BSE within the U.S. cattle population. Based on this analysis, we can definitively say that the incidence of BSE in the United States is extremely low. APHIS continues to conduct an ongoing BSE surveillance program targeted to high-risk animals that samples approximately 40,000 high-risk animals annually. This level of surveillance significantly exceeds the guidelines set forth by the World Animal Health Organization, which has affirmed that U.S. regulatory controls against the disease are effective.

It is because of the strong system that the United States has put in place that we can be confident of the safety of our beef supply from BSE and that the spread of BSE has been prevented in this nation.

FURTHER ACTIONS

The investigation led by OIG with support from FSIS and AMS is ongoing. However, we are not waiting for the completion of the investigation to act.

USDA has already taken a number of steps to strengthen our inspection system. As I mentioned above, pending the conclusion of the investigation, USDA has implemented a series of interim actions to verify and thoroughly analyze humane handling activities in all federally inspected establishments.

FSIS has increased the amount of time allocated per shift by inspection program personnel to verify humane handling activities and to verify that animals are handled humanely in ante-mortem areas. FSIS is also conducting surveillance activities to observe the handling of animals outside the approved hours of operation from vantage points within and adjacent to the official premises. A notice has been issued to all FSIS inspection program personnel to reinforce the work methods for conducting humane handling verification activities at all levels and to ensure the greatest utility of the Humane Activities Tracking System (HATS) program. This began on March 3.

Surveillance and inspection activities are being prioritized and focused based on existing data such as the category of livestock handled at the facility, humane handling data, observations made at the facility during regular inspection and a plant's operating schedule.

FSIS will continue to collect information in HATS, which provides an accounting of the time spent by FSIS inspection program personnel performing specific tasks and the results of that inspection related to humane handling and slaughter. Starting on March 4, 2008, FSIS inspection program personnel assigned to Federally inspected livestock slaughter establishments increased the amount of time that they spend conducting HATS activities from anywhere between 50-100 percent. This increased HATS inspection will continue for 60 days and will be closely measured during that time.

Prioritization will help to ensure the optimal use of resources to ensure humane handling and food safety. FSIS is focusing surveillance and inspection activities at establishments where older or potentially distressed animals are slaughtered, such as facilities that handle dairy or veal cattle. At these facilities, the time spent performing HATS activities will be doubled. At facilities with contracts from the AMS for nutrition assistance programs, regardless of the type or class of the animal slaughtered, HATS verification time is being doubled. At facilities where non-ambulatory livestock are infrequently presented, such as in slaughter facilities that handle young market classes including steers, heifers, market hogs, and lambs, an additional 50 percent of HATS verification time may be required. At least once every two weeks, a District Veterinary Medical Specialist or a district analyst is verifying that inspection personnel at each official livestock slaughter establishment are conducting the appropriate increase in HATS verification time. Any plant found not to be in compliance will be reported to the in-plant supervisor and the frontline supervisor.

Meanwhile, FSIS will begin reviewing the HATS to determine what, if any, adjustments are needed to maximize its utility as a tracking tool to improve compliance.

FSIS is currently auditing all 19 beef slaughter establishments that participate in AMS's nutrition assistance program. This is the first in a set of audits we will be conducting. We expect to complete that audit by the end of the week, when we will begin to analyze the results.

The investigation being led by OIG with support from FSIS and AMS is ongoing. Once the investigation has concluded, we will have additional information that, along with the results of the additional verification activities, will determine the actions for FSIS oversight, inspection and enforcement that may be required.

EFFORTS TO FIGHT FOODBORNE PATHOGENS

In addition to BSE, I wanted to take this opportunity to report to the Subcommittee some of the Agency's activities regarding some specific foodborne pathogens. Based on Centers for Disease Control and Prevention's (CDC) annual FoodNet data report, we are making some progress toward meeting the Healthy People 2010 goals regarding the incidence of foodborne illness, though we know we still have work to do to further reduce foodborne illness.

FSIS' verification sampling is a critical method the agency uses to collect data and is a good example of how we have taken a more risk-based approach. The agency's verification sampling program, FSIS samples meat, poultry and processed egg products and analyzes them for the presence of microbial pathogens. However, the agency has paid particular attention to E. coli O157:H7 in raw ground beef and salmonella in raw meat and poultry products through the E. coli O157:H7 initiative announced last fall and its ongoing salmonella strategy.

The new, ongoing actions we have undertaken to protect the public against the risk of E. coli O157:H7 include expanded testing. By March 2007, FSIS had already begun testing trim, the primary component in ground beef, in addition to ground beef itself. However, as a result of an increase in E. coli O157:H7-positive samples, the subsequent increase in the number of E. coli O157:H7-related recalls, and the increase in human illnesses linked to these recalls, FSIS implemented a number of initiatives to combat E. coli O157:H7.

In July 2007, after an unusual number of E. coli O157:H7 positives the month before, FSIS substantially increased the number of raw ground beef samples scheduled for July from 1,100 to 1,943—an increase greater than 75 percent. After seeing nothing unusual in the positive sample rate in July, FSIS began scheduling samples for every raw ground beef establishment once per month (i.e., approximately 1,350 samples per month).

On October 26, 2007, FSIS inspection program personnel began testing additional components of ground beef. By testing earlier in the production chain, FSIS minimizes the likelihood that this contaminated source material will be used in ground beef that is available to consumers. FSIS began requiring countries whose beef is imported to the United States to conduct the same trim and beef component sampling or an equivalent measure, and the agency has begun verification sampling of trim at ports of entry to supplement the agency's sampling of ground product at ports of entry. We will be analyzing imported and domestic product test results to determine whether we need to make further changes to FSIS policies and programs.

Other key initiatives targeted to Federally-inspected plants that produce raw beef products include verifying control of E. coli O157:H7, the creation and use of a new checklist for verifying control, targeted sampling for E. coli O157:H7 at slaughter and grinding facilities based on production volume and pathogen controls, follow-up sampling of 16 samples and conducting food safety assessments for plants with a Federal or State positive E. coli O157:H7 test result, and refinement of the agency's E. coli O157:H7 test method to provide a more sensitive test that will detect E. coli O157:H7 at even lower concentrations. All of these policy changes mean that FSIS will be better able to identify an emerging problem as early as possible and will be able to prevent contaminated product from entering commerce.

The agency is completing a more in-depth analysis of the data captured in responses to questions, filled out by FSIS inspection program personnel, about reassessment of HACCP plans related to E. coli O157:H7. Our preliminary data, completed in November 2007, shows that almost 96 percent of all beef slaughter and processing establishments reassessed their HACCP plans. We are analyzing these responses, and we anticipate that the analysis will lead to new policies, directives, or possibly rules and regulations.

In the wake of these progressive E. coli O157:H7-related policy changes, FSIS determined that steps were also needed to ensure that inspection program personnel and the industry fully understand the nature of the challenge presented by E. coli O157:H7. We are developing a strong, ongoing strategy to evaluate the success of our training program. Through the In-Plant Performance System, AssuranceNet management controls, and reports from district analysts, the agency is ensuring that inspection program personnel are doing their jobs correctly, are held accountable, and have appropriate workloads and supervision.

As with any policy or program change, FSIS is making sure that we educate and receive feedback from our public health partners and stakeholders regarding our E. coli initiatives. For example, on October 17, 2007, FSIS, FDA, and CDC hosted a public meeting regarding E. coli serotypes other than O157:H7 that are related to foodborne illness. In October and November, 2007, FSIS targeted outreach and training sessions around the country for small and very small raw beef processors. On January 23, 2008, FSIS participated in a meeting with the American Meat Institute Foundation and the National Meat Association about E. coli O157:H7 surveillance and prevention.

We will continue to work to identify the cause of the recent increase in E. coli O157:H7 illnesses and recalls, and to find a permanent, workable solution to the issue. Thus, we are planning a public meeting for April 2008, focused on a discussion with representatives from science, academia, industry, consumer groups and government, about the increase in illnesses and recalls attributed to E. coli

O157:H7. This meeting will provide updates on FSIS initiatives and build a foundation for establishing solutions to address the challenges posed by this pathogen.

In mid-May, FSIS will hold a meeting with its State and local public health partners, including FDA, CDC, industry and consumer groups, about how to improve the effectiveness and efficiency of outbreak investigations and recalls conducted by FSIS in collaboration with these partners. Every E. coli O157:H7-related recall last year showed me something that we can improve, and I hope that these meetings will get everyone to start thinking about how to improve the coordination, accuracy, and timeliness of communication and food safety activities, specifically outbreak investigations and recalls.

Another important step in that direction is USDA's announcement on February 5, 2008, that the Department agreed to grant a conditional license to Bioniche for its E. coli O157:H7 Cattle Vaccine. This is the world's first vaccine that may be used as an on-farm intervention to reduce the amount of E. coli O157:H7 shed by cattle.

It is important to keep things in perspective. Although last year we observed a rise in E. coli O157:H7-positive samples and recalls, because of new policy implementation and closer oversight and by working with industry, USDA has made tremendous progress in controlling E. coli O157:H7 overall. In fact, between 2002 and 2006, FSIS testing shows the percentage of samples testing positive for E. coli O157:H7 declined by 78.3 percent. During this time there was also a reduction in illnesses attributed to E. coli O157:H7. There was a slight increase in 2006, but several of those illnesses were attributed to food outbreaks that were not related to meat products.

FSIS instructed plants to reassess their food safety plans in 2002. As a result of industry's hard work and commitment to making safer products, we saw the rates of positive samples decrease in 2002, 2003 and 2004, remaining at 0.17 percent for 2005 and 2006. To put that percentage into perspective, out of 12,000 samples taken in 2006, only 20 were positive for E. coli O157:H7.

Although we ended 2007 with 21 recalls due to E. coli O157:H7, the percentage of E. coli O157:H7 positive samples for 2007—0.23—was still well below the percentage of positives during the 2000—2003 timeframe.

As another part of the agency's verification sampling program, FSIS collects and analyzes samples of raw meat and poultry product for salmonella. In response to this continued foodborne threat, in February 2006, FSIS announced an 11-point, risk-based strategy for salmonella reduction in raw products. The initiative included targeting resources at establishments with higher levels of salmonella and changed the reporting and utilization of FSIS' salmonella verification data test results.

We can easily see the positive results of this risk-based strategy. If we compare the plant categories based on broiler carcasses analyzed for salmonella in 2006 to 2007, we see that the percentage of plants in Category 1, or those with sampling results amounting to half or less than half of the current standards, increased dramatically, from 49 percent to 74 percent. Likewise, the percentage of plants in Category 3 decreased significantly from 10 percent to two percent. Essentially, the percentage of young broiler carcasses that tested positive for salmonella decreased by 50 percent—from 16 percent to 8 percent.

Earlier this year, FSIS announced further changes in its salmonella policy to continue driving down the incidence of salmonella in poultry. On March 28, 2008, the agency will begin posting on its Web site completed verification test results from establishments performing in Category 2 or 3, beginning with young chicken slaughter establishments. The agency will also offer specific waivers to Category 1 establishments. With these waivers, those establishments with the lowest salmonella rates will be able to test new procedures, equipment, or processing techniques that will facilitate improvements in the ongoing control of salmonella.

COORDINATION WITH PUBLIC HEALTH PARTNERS

In conjunction with CDC, FDA, and epidemiologists and public health laboratories in several States, FSIS continues to build upon existing data in the Foodborne Diseases Active Surveillance Network, or FoodNet, which conducts active surveillance of foodborne diseases, case-control studies to identify risk factors for acquiring foodborne illness, and surveys to assess medical and laboratory practices related to foodborne illness diagnoses. FoodNet data are also used to evaluate progress toward meeting CDC's Healthy People 2010 national objectives for foodborne infections.

A sister system of FoodNet is PulseNet, a collaborative national computer network of public health laboratories that link seemingly sporadic illnesses together and enable public health officials to more quickly identify and respond to multi-State illness outbreaks. In fact, through the use of PulseNet, we are able to identify seemingly unrelated foodborne illnesses as actual outbreaks more quickly. Prior to

PulseNet, many of these outbreaks would not have been recognized as outbreaks. These two systems allow agencies to collaborate and bring their specialized knowledge together to better protect public health.

FSIS also takes every opportunity to diversify and improve the data submitted to CDC's PulseNet. On August 30, 2007, FSIS and the Agricultural Research Service (ARS) signed a memorandum of agreement in order to share data on salmonella. Specifically, the cooperative agreement served to set requirements related to the submission of salmonella strains and carcasses from the FSIS/Pathogen Reduction, HACCP Verification, Baseline, and other programs to ARS for testing. ARS tests include Pulsed-Field Gel Electrophoresis, which helps to determine the so-called DNA fingerprint of a pathogen; antimicrobial susceptibility tests; and other laboratory sub-typing procedures.

We are committed to working with all of our food safety and public health partners to use the data that is available and seek more data to be able to attribute illnesses to specific foods. To cite one important example, we held a public meeting in April 2007 with our stakeholders and partners and engaged them in a discussion about the importance of foodborne illness attribution data, how this data is being developed, and how it is being used. Because we believe attribution is important in public health decision making, we are pioneering the use of attribution data in our evolving public heath risk-based approach to inspection.

How FSIS Ensures the Safety of Imports

I know another area of interest for the Subcommittee is how the Agency ensures the safety of imports. FSIS uses a comprehensive system to ensure that imported meat, poultry, and processed egg products are safe and secure. The three-part system includes a thorough analysis of each country's food laws and inspection systems to determine initial equivalence; on-site audits of each country's food safety system to verify that the system is implemented in accordance with what is in writing, and then to ensure equivalence is maintained; and port-of-entry inspection on all FSIS-regulated meat, poultry, and processed egg products coming into the United States, with a few exceptions. The amount of FSIS-regulated meat and poultry imports has remained approximately the same over the past five years, hovering around four billion pounds of meat and poultry from 29 of the now 34 eligible countries, approved through rulemaking.

In addition to the initial re-inspection of product entering the United States, FSIS performs intensive random re-inspection on approximately 10 percent of the shipments of meat and poultry products. These re-inspection tasks include product examinations, microbiological analysis for pathogens, and/or a test for chemical residues.

Approximately five percent of shipments of imported meat and poultry products receive microbiological and chemical verification testing. This system is enhanced by FSIS' Import Surveillance Liaison Officers, who conduct a broad range of surveillance activities at import facilities and in commerce, and serve as liaisons to improve coordination with other agencies like U.S. Customs and Border Protection.

Access to the U.S. Customs and Border Protection's Automated Commercial Environment (ACE) database has provided FSIS a more targeted approach to identifying and controlling ineligible entries of FSIS-regulated product closer to the entry point, rather than after its release into commerce. In FY 2005, prior to FSIS' use of the ACE system, the amount of ineligible product removed from commerce that did not pass through import houses was a little over 36,000 pounds. In FY 2006, this amount increased to 1.6 million pounds, and in FY 2007, 2.1 million pounds was identified, destroyed, or redirected to FSIS for re-inspection.

Interagency Working Group on Import Safety

Recently, I represented USDA in the Interagency Working Group on Import Safety, helping to determine which aspects of the U.S. food safety system can be strengthened. The President formed this Working Group to conduct an across-the-board review of import safety by U.S. importers, and by Federal, State, and local governments. It was also given the task of providing recommendations to the President that will help to further improve the safety of imported products.

In September 2007, the Working Group issued a strategic framework for doing more to ensure the safety of imported products. This framework outlines a risk-based approach that includes the principles of prevention, intervention, and response. The framework supports USDA's long-standing approach to evaluating and verifying the ability of foreign food safety systems to meet food safety requirements for meat, poultry, and processed egg products exported to the United States.

On November 6, 2007, the Working Group released an implementation action plan containing 14 recommendations and 50 action steps. The Working Group provided specific short- and long-term recommendations for import safety improvements and reflected stakeholder input received through several outreach activities, as well as from a public meeting that was held on October 1, 2007, at USDA headquarters here in Washington. The Administration is working toward implementation of the Working Group's recommendations. Progress is being measured by each action step.

CONTINUED EVOLUTION OF INSPECTION AND USE OF RISK

Because of my medical background and passion for public health, I have pursued the issue of how best to use risk in inspection. It has been a healthy debate. I believe this open and frank debate on risk needs to be expanded to include all foods.

We need to continue to pursue these looming questions: Where is the risk greatest and where do inspection and other resources belong? Not all food products are equal from a risk standpoint. I am encouraging all food safety partners to join together and assess all foods and ensure that we are getting the best return for the Federal investment in food safety for the American public.

Higher risk products and processes would appear to warrant a higher level of effort to ensure measures are in place and put into action to control pathogens, lowering the likelihood of foodborne illness. While inspection may be critical for some plants and products, a system of audits may be acceptable for products with less inherent risk, or processes with less risk or hazards, where established methods have proven effective to control pathogens.

We need to develop a uniform, consistent process to determine when and where inspection is warranted, based on the inherent risk of the product and a plant's demonstrated control of that risk, and when and where audits are sufficient. I hope that we will collectively ask the tough questions and come up with answers for a new approach to inspection based on public health and risk.

CONCLUSION

FSIS is committed to improving its approach to inspection to focus on public health and risk. As a medical doctor and a public health professional, I believe that what all of us with a stake in food safety must accomplish is protecting people, especially those most vulnerable to a foodborne illness—the very young, the elderly, the immune-compromised and pregnant women.

Again, thank you for the opportunity to appear before you today. I am now happy to take your questions.

Mr. STUPAK. Thank you. The Federal Register which had those classifications were made part of the record earlier because there was some confusion on different classes so thank you. I said in my opening though that one of the things I try to do as chairman and members of this subcommittee, when we have companies, government agents, and agencies and other individuals come before the committee we expect them to follow through on promises they make. And we will do a follow-up. We will bring them back if we have to. So let me start, Mr. Raymond, with a matter last year in November, at our hearing last November. Mr. Inglejohn, who is here today, testified about approving carbon monoxide packaging. And we pointed out that the studies that microbial submitted as part of the approval process were flawed, and we were told that Mr. Inglejohn said he would re-examine FSIS approval and get back with us because there was denial and it wasn't—whether it was treated with carbon monoxide or not the microbials were going down and the studies were flawed. We acknowledged that on the record.

So whatever happened, how come you haven't got back with us? Have you reviewed that study that we brought up in November?

Dr. RAYMOND. I don't know why we didn't get back to you but I commit to you and promise to you that we will very shortly. I

know we have re-looked at all the data between that testimony and today, and we have found continuing evidence that the microbials do go down in number and time in products treated with the MAP program.

Mr. STUPAK. But it showed the same thing without the MAP program too, so that was the flaw we were showing. But anyway, when will you get back to us? Give me a date. When can you get back to us on this?

Dr. RAYMOND. Two weeks.

Mr. STUPAK. Two weeks. OK. I am going to hold you to that. In early February you mentioned Westland/Hallmark. How did you learn about this Westland/Hallmark? Were you notified by the Humane Society? How did USDA learn of this?

Dr. RAYMOND. The Washington Post informed us, sir.

Mr. STUPAK. OK.

Dr. RAYMOND. That they had the videotapes.

Mr. STUPAK. OK. And did you see the videotapes?

Dr. RAYMOND. Yes.

Mr. STUPAK. OK. Have all the videotapes been turned over to USDA?

Dr. RAYMOND. I don't know that all videotapes they have in their possession have been turned over. I cannot say that.

Mr. STUPAK. Were you here today when we showed the earlier videotapes?

Dr. RAYMOND. Yes, I was, sir.

Mr. STUPAK. You have seen those prior to today's hearing?

Dr. RAYMOND. Yes, I have.

Mr. STUPAK. They have been in the public domain for some time, right?

Dr. RAYMOND. I know the first one has. I will be honest with you, I have not seen the second one in the public domain. That is not to say that it is not. I don't mean to be——

Mr. STUPAK. Sure. Did USDA find that Westland/Hallmark illegally slaughtered downed cattle? Have you made that finding?

Dr. RAYMOND. If I might, I would also like to clarify the definition of downer. A downer cow is a cow that when it presents for antemortem inspection cannot rise on its own and ambulate. That technically is a downer cow. Cattle that have been inspected by the veterinarian, both at rest and in ambulation, in movement, to be fit for the food supply may for whatever reason not be able to get up later, and as you heard earlier, if the veterinarian inspects that animal and can determine that it is due to an acute—it can go in the food supply.

Mr. STUPAK. Correct.

Dr. RAYMOND. That is not what we would call a downer. We would call that a non-ambulatory.

Mr. STUPAK. OK. During USDA's inspection, did you find Westland/Hallmark illegally slaughtered non-ambulatory cattle?

Dr. RAYMOND. Yes, we did, sir.

Mr. STUPAK. And since 2004, I think the records showed earlier, that has been U.S. law, you cannot slaughter——

Dr. RAYMOND. January, 2004, an interim rule was put into action.

Mr. STUPAK. OK. Let me ask you this. You saw the videos today. Were any of the cattle that we saw or cows in the video today, were they slaughtered illegally based on the videos you saw today?

Dr. RAYMOND. They were slaughtered in non-compliance with our regulations, yes, sir.

Mr. STUPAK. OK. At our previous hearing, we heard testimony that the USDA veterinarian who conducted the antemortem inspections at Westland/Hallmark only inspected cattle twice a day, 6:30 a.m. and 12:30 p.m. That was on the first video we saw today. Further, he performed these inspections the same time every day according to the videos. What was that inspector doing then the rest of the day?

Dr. RAYMOND. First of all, the statement that he inspected the animals only 6:30 and 12:30 comes from the Humane Society. We are doing our own investigation to determine the accuracy of that statement. Our inspectors, veterinarians and other inspectors, are instructed to go out into the pen area periodically during the day at different times unannounced to observe handling. But to answer your question, the public health veterinarian in this particular plant also has other duties that are off line that take him into the plant not the least of which is examining all the carcasses postmortem.

And it wasn't mentioned this morning but about 20 carcasses per day in that plant are condemned postmortem because he sees things once the hide is off that would pull that animal out, so that is one of the very important things that he does plus other, the HASA procedures, the SOSP procedures.

Mr. STUPAK. How many inspectors did you have at Westland/Hallmark?

Dr. RAYMOND. Five, sir.

Mr. STUPAK. And have some of them been disciplined as a result of your investigation at Westland/Hallmark?

Dr. RAYMOND. I cannot talk about personnel issues at this particular point in the investigation.

Mr. STUPAK. The question was were they disciplined, yes or no.

Dr. RAYMOND. I can't discuss personnel issues at this point in time in the investigation.

Mr. STUPAK. According to the newspapers, three of them were disciplined. Any reason to say that newspaper was wrong?

Dr. RAYMOND. I really can't discussion personnel issues.

Mr. STUPAK. All right. What type of surveillance was there in the cattle pens when the inspector was not there? Do we have any—if an inspector isn't there, is there any USDA inspection going on in these cattle pens?

Dr. RAYMOND. Not on a continual basis, no.

Mr. STUPAK. You mentioned you were a professional public health officer. Professor Olson mentioned that before FDA—I know it is an FDA question but for 9 years they have had this petition going since 1999 on irradiation. As a professional health public official, wouldn't you want to see that petition acted upon on irradiation? Should it take 9 years?

Dr. RAYMOND. The beef are USDA also so I find a lot of things about the Federal government as a public health official to be slow and sometimes that is good because everybody gets a chance to

have a voice and explain their thoughts and so forth. I do find it problematically slow as a public health official, including at the USDA.

Mr. STUPAK. Right. And now you are part of the government so——

Dr. RAYMOND. Yes.

Mr. STUPAK [continuing]. Wouldn't you expedite and try to get that process moving forward instead of 8 or 9 years?

Dr. RAYMOND. Yes, sir.

Mr. STUPAK. Because I think as the professor said if it wasn't for public health officials, we probably wouldn't have had pasteurization and other advances in science and technology. It has been reported that—it is going into a personnel issue again but let me try it. Supervising veterinarian at Westland/Hallmark had worked on site for 20 years. It has also been reported that in the 1990s Hallmark faced scrutiny for the way it handled downer cattle. Further, in 2005 as testimony showed today USDA cited the company for non-compliance for being overly aggressive in using electric prods to move cattle. If the veterinarian was present during these times why wasn't he putting forth these complaints or being more diligent to make sure that downer cows or cattle were not being mistreated or illegally slaughtered?

Dr. RAYMOND. If our veterinarian had seen any of these actions that plant would have been—the inspection would have been suspended, and that plant, as we did in 12 plants last year when our public health veterinarians or other inspectors did see egregious inhumane handling, we do take it serious and we did shut 12 plants last year because of it. He evidently did not see it in this plant, but again that is part of the investigation.

Mr. STUPAK. I mentioned he has been there for 20 years. So, Dr. Raymond, USDA inspectors are often assigned to facilities for years on end. Do you believe that this practice can compromise their role as a regulator? In other words, does their loyalty shift from the government to the company they are supposed to regulate?

Dr. RAYMOND. I understand your question, and I would certainly hope that would not because of the levels of supervision that they have. They are not out there all by themselves. They have supervisors that overlook their work. The in-plant inspector in charge is overlooking a line inspector. We have the district managers, deputy district managers all the way to the assistant administrator for the office of field ops.

Mr. STUPAK. Let me ask you this, and then I will it turn over to my friend, Mr. Shimkus, for questions. There has been an alarming jump in the number of recalls and illness associated with E. coli contaminated meat. In 2007 alone there were 21 recalls of meat products due to being tainted with this deadly pathogen. These recalls affected about 33 million pounds of meat. And then you look back one year to 2006 with E. coli contamination, we had 8 recalls and just over 155,000. Why the dramatic increase?

Dr. RAYMOND. I think that is a multi-part answer, sir, and it does concern me greatly, and that is why we have announced several new E. coli initiatives including several meetings with other experts, scientists, industry, consumers, et cetera. But to try to answer your question, there are several factors. One, we have a more

sensitive test when we test for E. coli. Half of those 21 recalls were due to product tested positive. We tested, and we have a more sensitive test now. I think you are going to continue to see that part of recalls increase as this test gets more widely used, number 1.

Number 2, we changed the way we do recalls last year. I was unhappy with some of the—I don't know if you want to call them policies—that FSA has had in place, that they did not do recalls until certain things all lined up. And I said that is too long. As a public health official, I can't wait that long. We are going to do them quicker, and so we did some recalls last year that would not have happened the year before. I think we do a better job of linking seemingly unrelated illnesses together because of Pulse Net, which I referenced very briefly in my opening comment. That is a technique that allows us to take a case of E. coli foodborne illness in Minnesota and link it to one in Michigan and hopefully find the product and we do the recall. We couldn't have done that 10 years ago. That didn't all happen last year. I am not saying that is why last year, but we do a better job there.

I do believe the health professionals are doing much more testing than they used to when people do have signs and symptoms of foodborne illnesses. We work hard with them for 3 years telling them the more tests you do the better attribution we can get, the better attribution we have the better we can find what the solutions are to fix this problem. A lot of physicians and other health care professionals were reluctant to order a stool culture for the cost if the patient didn't look that ill so we are seeing twice as many tests being done as we did just a couple years ago, and, quite frankly, the patients are more concerned about this, the victims. The people that get the GI symptoms are thinking foodborne illnesses because of all the publicity and they run to the health care provider more quickly and they get attention more quickly, so I think the numbers are up because of those reasons.

All that said, the product testing went up last year, pure and simple. It went up last year. I believe personally, and I have no science to back this up. I will tell you right now this is Raymond's theory that the E. coli load on the cattle has gone up, and I believe the interventions that we have in place in the plants are now being overwhelmed by a higher number of contaminants of E. coli on the hides and ultimately on the carcasses and in the intestines of these animals. We need to get that number down or find better in-plant interventions or use irradiation as you have already heard. I don't believe industry got sloppy and I sure don't believe our inspectors fell asleep at the switch. I do believe the load became higher because of changes in the feed, changes in the environment, maybe changes in the bug itself. Maybe it has developed a resistance. Some of the lactic acid washes, for instance, that we use, same as staphylococcus has developed a resistance to penicillin. Bugs do do that.

Mr. STUPAK. OK. That was Raymond's theory. Answer me this one, Stupak's theory. What happened here with Westland/Hallmark here? What happened? You call them up. You gave them 4 to 5 hours the testimony was and they agreed to the recall even though you had a 10-day period. And they asked for the video that you said that USDA had, and according to Mr. Mendell he never

saw that video. What convinced Hallmark to do the 140 million pound recall based on a phone call? What else did the USDA have that would a company where this gentleman spent his whole life building up basically go down based on a phone call, what else is there? How are you that convincing? What are we missing?

Dr. RAYMOND. There are no smoking guns if that is what you are after. We obviously interviewed many employees and also not just employees, the plant and our employees, but also the truck drivers that hauled the cattle there, the buyers that bought the cattle. We threw out a wide net and interviewed a lot of people, and we found evidence. Allowing an animal that became acutely disabled to go into the food supply without being inspected by the public health veterinarian was not an isolated incident. It was not a common incident but it happened enough that we knew we had a problem. We told the gentleman that. We did not show him the film that day. We had to look at it because of the investigation but he didn't ask a second time.

But I want to clear up the 10-day thing also. We didn't say do it in 10 days or it will be worse. What we said was you can do a voluntary recall now or tomorrow we will detain the product and in 10 days we begin the process to detain it. But we would have gone into action the next day.

Mr. STUPAK. So it was based upon your investigation that it was more than just the 2 cows we pointed out today.

Dr. RAYMOND. Yes.

Mr. STUPAK. OK. Thank you. Mr. Shimkus. Sorry I went over my time there.

Mr. SHIMKUS. You are the chairman and you have the gavel. A couple questions, and as prepared as I want to be because of the questioning and answering, I am scattered all over the place, so let me start with this. The 12 plants that were closed down last year, what is their status today?

Dr. RAYMOND. They are operating.

Mr. SHIMKUS. And have you, the USDA, have you—in the last hearing I talked about there was I think from USDA 12 facilities operating, 10 were positive, I mean 10 were found to have problems, 2 had slaughtered downed cattle. In the OIG inspector's report, that issue. I mean it does make the case that 10 were fine. There are always problems. Let me go to the question my chairman mentioned. I understand you can't answer personnel questions but a follow-up on this. Is the investigation ongoing?

Dr. RAYMOND. Yes, sir.

Mr. SHIMKUS. That is why you are not going to answer it?

Dr. RAYMOND. Yes, sir.

Mr. SHIMKUS. OK. Then that is a better response than it is over and we just don't want to tell you. Let me go to it. This is also another follow-up question. What specific evidence did USDA have in early February against Westland/Hallmark to warrant this recall? Was it just the public videos we have seen today or did USDA have conclusive evidence that these downed cows were slaughtered and that their meat entered the food supply and was sold to customers?

Dr. RAYMOND. Our decision to ask them to do a voluntary recall was based on not only the video but also on multiple interviews with plant employees, our employees, and other providers around

the plant. The video, when we saw the video what that really did was authenticated the interviews that we had done which at that point in time was sworn testimony but yet to shut a plant down of that size and do what we did the video authenticated the interviews and that is when we took action.

Mr. SHIMKUS. Do you have any evidence that the meat entered the food supply and was sold to customers?

Dr. RAYMOND. Yes, sir. I mean Mr. Mendell made the comment that some of those animals may have been condemned postmortem. Of course, I don't know which ones were in those 20 but we certainly cannot say it did not enter commerce. I think it is a reasonable statement to assume it did enter commerce, some of it. I don't know that.

Mr. SHIMKUS. You don't know that either. You don't know that it entered. You don't know that it did not enter. And is that why it is a class 2 versus a class 1?

Dr. RAYMOND. No. The reason it is a class 2 is because the risk of that—the animal you saw in the video, let us just assume for a moment that it went into commerce.

Mr. SHIMKUS. But we don't know that. That is the whole point. We don't know that it actually went in. I mean you are making an—part of my other line of questioning was it would be better for me to have a tape that said here is the cow coming off the truck, they are doing everything bad and evil and malicious and inhumane. They drag it into the kill box. The animal gets killed. The animals gets processed. It goes past the postmortem inspection and it has been ground up and it is in hamburger. But we don't know that. I hear there are more tapes but I don't—it is a You Tube generation but I can guarantee you I am not You Tubing for meat processing recall. Maybe I should as ranking member. Maybe that is what I should be doing at night. But I hadn't seen that second tape.

Dr. RAYMOND. If I may. When the investigation is complete, you will see evidence that will assure you we did what we had to do, number 1. Number 2, this product entered that establishment in violation of our regulations, and our regulations are there for a reason and that is to protect the food supply as well as we can. It entered the food chain in violation of our regulations. That is why it is a class 2.

Mr. SHIMKUS. Does a class 2 mean that it is a public health threat?

Dr. RAYMOND. There is a remote probability that consumption of this product may cause serious adverse health events.

Mr. SHIMKUS. I will give back the balance of my time.

Mr. STUPAK. OK. Mr. Whitfield for questions, please.

Mr. WHITFIELD. Yes. Thank you, Mr. Chairman. Mr. Raymond, in your testimony on page 1 you indicate all of the various acts that FSIS enforces, and you also say that it enforces the Humane Methods of Slaughter Act, which requires that all livestock at federally inspected establishments be handled and slaughtered in a humane way. Now all of the testimony indicates that this Hallmark plant was closed at Chino because it violated FSIS regulations and there was a class 2 recall because there was a remote possibility that the meat was contaminated, is that correct?

Dr. RAYMOND. We initially suspended inspection at this plant on February 4 because of violation of the Humane Handling Act. It was subsequent to that that we suspended the inspection because of the illegal entry of the——

Mr. WHITFIELD. OK. So initially it was suspended because of the Humane Handling Act?

Dr. RAYMOND. That is correct, sir.

Mr. WHITFIELD. OK. And so you all take the Humane Handling Act very seriously just as well as you do the food safety?

Dr. RAYMOND. Absolutely.

Mr. WHITFIELD. OK. Now what kind of training do inspectors receive as it relates to humane handling?

Dr. RAYMOND. Depending what their inspection level is and where they would be working, there is variable degrees. First of all, the public health veterinarians, of course, that are mostly the ones that are going to be noting these activities are trained professionals. They have gone to veterinary medical school where they have been taught humane handling methods throughout their education and probably practiced them in the field for a while before they came to work with us. The other non-veterinarian inspectors are going to go through I don't know how many hours. I can find out for you and get back to you. I don't know the exact—but they all receive training. The on-line inspector is going to do a whole lot less looking for inhumane activities because he or she is in the plant and not out——

Mr. WHITFIELD. And how many inspectors are in that plant in Chino, how many inspectors were there?

Dr. RAYMOND. There were five inspectors, sir. Three were on-line and two were off-line.

Mr. WHITFIELD. So three on-line, two off-line, and then one veterinarian?

Dr. RAYMOND. I included the public health veterinarian in the two off-line. Sorry.

Mr. WHITFIELD. OK. Now you said that a downer cow is a cow that at the point of antemortem inspection cannot be ambulatory, is not ambulatory.

Dr. RAYMOND. That is correct, sir.

Mr. WHITFIELD. At what point is the antemortem inspection made?

Dr. RAYMOND. It is made before the animal is allowed to enter the knock box. It is generally made some time the day of slaughter. It may be a few hours before the animal actually goes to the knock box.

Mr. WHITFIELD. So that point is right next to the knock box, it is right there?

Dr. RAYMOND. It is in the yard. It is in the pens. Depending on the size of the plant. There may be a plant that slaughters 10 cows a day and it would be right next to it. In a large plant it might be 10 pens away.

Mr. WHITFIELD. But if a cow went past that point and was ambulatory and then for some reason the leg was broken and went down in order to get it to the knock box they would have to move it some way.

Dr. RAYMOND. It would have to be humanely handled after the veterinarian came out and examined it at the spot where it went down and determine——

Mr. WHITFIELD. And how would they move it after the leg had been broken to the knock box?

Dr. RAYMOND. They would stun it and then basically move it while it was unconscious into the knock box.

Mr. WHITFIELD. So they would make it unconscious and move it?

Dr. RAYMOND. Yes.

Mr. WHITFIELD. OK. Now on March 3 you all initiated this new program called Humane Activities Tracking System, is that correct?

Dr. RAYMOND. Did you say on March 3?

Mr. WHITFIELD. That it began on March 3.

Dr. RAYMOND. It actually began several years ago. March 3, what we did was we gave directives to our work force to increase the amount of time they spent on the humane animal treatment tracking system, humane animal tracking system. But we did that in an effort to find out if what happened at Hallmark was an isolated incident or whether it was something that was more pervasive, so we doubled the amount of time that we spend on these HATS activities, that is humane handling activities. There are nine things we look at.

Mr. WHITFIELD. So this activity's tracking system is an old program but you just beefed it up on March 3?

Dr. RAYMOND. Yes.

Mr. WHITFIELD. All right. And what does that mean, beef up, what does that mean?

Dr. RAYMOND. For the plants that are producing product for the school lunch programs, for instance, or any other federal commodity programs, we will spend twice as much time doing these HATS activities in those plants for the next 60 days. For plants that deal with primarily old cows like this plant they will also increase the amount of activity from 50 to 100 percent a time, and then in the fat cattle we will increase it up to 50 percent of the time because——

Mr. WHITFIELD. How does this system relate to the computerized tracking system?

Dr. RAYMOND. This is it.

Mr. WHITFIELD. This is the computerized tracking system. OK. All right. One other question. Dr. Sundlof, if you were a Rotary Club in my home town, for example, how would you explain the interaction between FDA and the Department of Agriculture as it relates to food safety? You are responsible for food safety. They are responsible for food safety. So what is the interaction here?

Dr. SUNDLOF. Thank you, Congressman. Well, the simple answer is that the USDA is responsible for the safety of meat and poultry, and FDA is responsible for virtually everything else. I think there are some processed egg products that USDA is also responsible for, and I hope I got that all right, Dr. Raymond.

Mr. WHITFIELD. But how often is it, I know I am going over my time a little bit, but I know that FDA has some regulations that certain animals will not be slaughtered for human consumption if it is found that they contain 1 of 12 or 13 chemicals, for example.

Dr. SUNDLOF. Right. The law says, and this is how we interact with the U.S. Department of Agriculture, that drugs can only be used in food-producing animals if, first of all, they are approved by the Food and Drug Administration. And, secondly, if the remaining residues of those drugs in the animal fall below a predetermined level after a certain time period which we regulate by assigning what is called withdrawal time, so after the last time the drug is given there has to be a waiting period before those animals can be processed into food. The animals at slaughter are actually tested by the Department of Agriculture, Food Safety Inspection System. They are analyzed for the presence of several, many more——

Mr. WHITFIELD. You mean when they arrive they are——

Dr. SUNDLOF. At slaughter they are usually—swabs are taken of the kidneys or liver or fat samples so——

Mr. WHITFIELD. In the postmortem?

Dr. SUNDLOF. Post-mortem.

Mr. WHITFIELD. And then those are analyzed?

Dr. SUNDLOF. Those are analyzed.

Mr. WHITFIELD. For every animal?

Dr. SUNDLOF. Pardon me?

Mr. WHITFIELD. For every animal?

Dr. SUNDLOF. Not for every animal. There are really two different programs, and I should let Dr. Raymond talk about this but there is a random sampling where we try and get an idea what the total population is and then there is a surveillance type sampling in which there are animals that look like they are high risk animals, and a lot of times dairy cattle are generally considered to be higher risk because oftentimes they are at the end of their life and they have been treated with drugs for disease.

But the USDA does the testing. If they find a residue violation then it is up to the Food and Drug Administration to take the enforcement action. And what we do is we go out to the establishment where the animal came from and try and trace that animal back to the farm of origin and try and understand why there was a residue issue, and if it is serious then we will take enforcement action and have often in the past.

Mr. STUPAK. Thank you, Mr. Whitfield. Mr. Raymond, if I may, in earlier testimony, or I should say the hearing, we had 2 weeks ago they talked about downer cow loophole. Some people feel, humane societies and others feel, that once it is a downer cow it should not go into the food supply at all even if inspected by a veterinarian. Your comment on that?

Dr. RAYMOND. I believe that an animal that has passed inspection, has been seen to ambulate in motion, does not appear to have any chronic health problems that then falls and breaks its leg, there is no reason that that presents a threat to the food supply of this country, and I believe they should be allowed to enter into the food supply. We have had this rule, as you mentioned yourself, since January of 2004. That is 4 years. This company violated the rule. I do not believe we should change the rule to affect 800 companies because one company violated the rule.

Mr. STUPAK. OK. I think I speak for all parents of school-age children and seniors and the elderly when I say that in light of the videos we saw today and Mr. Mendell's admissions today, I guess

we feel safer knowing that the meat has been recalled, and there is some testimony or comments were made that mad cow disease, that won't surface, or the incubation period could be as high as 13 years, is that right?

Dr. RAYMOND. That is correct.

Mr. STUPAK. So we may not know the outcome of all this for some time. We could have——

Dr. RAYMOND. There is that remote possibility which defines a class 2.

Mr. STUPAK. And let us say some surface 12 years from now, we wouldn't know if it was from Hallmark or wherever it came from, right, if someone came down with mad cow disease?

Dr. RAYMOND. Let me remind you that no one in this country has ever come down with a variant CJ disease from eating cattle that came from this country. We only had 2 cows test positive in the herd out of 759,000. It is extremely rare. Those cows were both born before the feed ban went into effect, which went into effect over 10 years ago. These cows were 4 to 7 years of age. That is when a dairy cow quits producing milk.

Mr. SHIMKUS. Mr. Chairman, in follow-up can we ask him when was that, what year?

Mr. STUPAK. What year is that?

Dr. RAYMOND. The 2 confirmed cases, the 2 confirmed cases have come since the cow went down in December, 2003. I don't know the exact dates but it has been since December, 2003, actually since June, 2004 when APHIS began their enhanced surveillance.

Mr. STUPAK. We just had one in Canada too actually on the day of the hearing, right?

Dr. RAYMOND. I am just talking to the American herd right now.

Mr. STUPAK. Pardon?

Dr. RAYMOND. I am just talking to the American herd right now. The American herd has not had any cattle found that have BSE that were born after the feed ban went into effect.

Mr. SHIMKUS. Mr. Chairman, can I follow up?

Mr. STUPAK. Sure.

Mr. SHIMKUS. And the age of the cows at that time? We are going back to these two. What was the age of the cows?

Dr. RAYMOND. They were born before the feed ban. That is what is really important. It is not the age. But I can sure get the age for you. I don't know the age.

Mr. SHIMKUS. You answered the question, maybe I asked it wrong, but it was before the feed ban?

Dr. RAYMOND. Yes, sir.

Mr. STUPAK. Let me go back, Mr. Raymond. Would the USDA have discovered this problem without the Humane Society's sting operation?

Dr. RAYMOND. I would like to say yes but obviously it was going on and we had not, so I don't know.

Mr. STUPAK. Prior to this being notified or receiving these videos or notification of the sting operation by I think you said the Washington Post, had USDA been investigating this plant for downer animals? You said there were rumors and this video just verified what you had——

Dr. RAYMOND. No, no. After we became aware of the video the things we had to do was confirm that this action actually took place at this plant. We had to make sure that there was non-humane handling at this plant before we took action, which we did on the Monday morning, the 4th. At the same time, we are interviewing because we felt if this happened, if this plant had that kind of wanton disregard for our Federal statutes, then how did we know they had the same—placed the same emphasis on SRM removals, for instance, which would be most important or the downer rule. So we began a very thorough investigation of this particular plant, and we had interviews that indicated that this process of allowing an animal that became disabled to go to slaughter had been going on for 2 years. The video gave us irrefutable evidence, and that is when we did the recall.

Mr. STUPAK. OK. Thank you. Mr. Sundlof, Dr. Sundlof, I don't want to leave you out. In your opinion, does the proposed 2009 budget for FDA provide adequate resources for the Center for Science and Applied Nutrition to protect the Nation's food supply?

Dr. SUNDLOF. Well, let me just say, Mr. Chairman, that we look at it as more or less a down payment. We have said last fall that we are starting out a new approach to food safety and that is really focusing on the prevention side looking at our import programs and starting to ramp up to a different way of approaching food safety. We received somewhere in the order of $42 million in addition to our fiscal year '08 budget in '09, that is what the President has requested. This is going to go to trying to get those programs to the state where we need to start to really build the programs after that.

Mr. STUPAK. So it is a down payment so it doesn't adequately address the financial needs we have for food safety?

Dr. SUNDLOF. We have a lot to do under the new food protection plan and the Import Safety Action Plan, and we haven't even begun to put pen to paper to determine what that budget is going to look like.

Mr. STUPAK. OK. Under the 1997 FDA Modernization Act, Congress required the FDA to implement an expedited status for food safety petitions. In 1999, the agency stated that the top priority would be given to petition design to decrease the risk of foodborne illness, is that correct?

Dr. SUNDLOF. I believe that is correct, yes.

Mr. STUPAK. FDA has approved irradiation for reducing pathogens in meat and poultry and for insect control and shelf life extension of fruits and vegetables. However, the FDA does not allow irradiation to be used for pathogen reduction in fruits and vegetables. In 1999 a petition to allow irradiation for path reduction in fruits and vegetables and other ready to eat foods was submitted to the FDA. Eight or 9, well, almost 9 years later now the petition is still pending. Why hasn't the FDA acted on that petition on irradiation?

Dr. SUNDLOF. My understanding, Mr. Chairman, is that the original petition, the 1999 petition, involved virtually all foods. As we start—and we took the approach that we were going to evaluate that petition and look at all foods under that petition. During the process of reviewing the information, we did find that in certain

foods the process of irradiation did result in the production of furans which are cancer-causing chemicals.

So what the approach is now is that we are looking at specific types of foods under that petition. Our first one, the one of highest importance right now is leafy green vegetables, and we are working—it is our Number 1 priority to get that out. There is work being done.

Mr. STUPAK. When will that be done on leafy green vegetables? Can you give us a commitment it is going to be done here in the next few months?

Dr. SUNDLOF. Well, I can tell you that we will complete our review, the center will complete its review within the next several—I can't tell you exactly how many months but certainly this fiscal year and we will try and do much better than that.

Mr. STUPAK. Well, this fiscal year is until September 30. You had it for 9 years.

Dr. SUNDLOF. We are talking here just about the——

Mr. STUPAK. Right, leafy.

Dr. SUNDLOF. Right.

Mr. STUPAK. Yes, leafy was there in 1999 and it is still there.

Dr. SUNDLOF. Right.

Mr. STUPAK. What about the suggestion that you put an irradiation plant by Salinas Valley? You had that 21 outbreaks in 10 years. Why weren't you—would that help solve this problem? Why couldn't we put an irradiation plant to get that leafy vegetables and the spinach crop that we seem to have an outbreak every 6 months. Why won't we do that?

Dr. SUNDLOF. Well, we don't—that would be up to the industry if they wanted to do that but first obviously they need——

Mr. STUPAK. FDA won't even do an epidemiology study to try to figure out the source. Every time we come someone thinks it is the water, someone thinks it is the cows around there. I mean that is our salad bowl as you guys all referred to it. After 21 outbreaks you would think you would be a little bit more aggressive in trying to figure this out and solve the problem.

Dr. SUNDLOF. Actually, Mr. Chairman, we are doing that. We have been working with the State of California, with the academic community in California, and with the industry to try and better understand how E. coli is transferring from the environment into the spinach and other leafy greens. We are also looking at GIS systems, so we are looking at the topography using satellite imaging to determine where the outbreaks have occurred in the past so that we can have a better idea from an epidemiological approach to understanding what are the conditions that led to this contamination so we can prevent it in the future.

Mr. STUPAK. OK. Let us go back to the irradiation of food. It is used in over 30 countries. It is endorsed by the World Health Organization, CDC, Codex, even the FDA has stated that irradiation is safe and effective in decreasing or eliminating harmful bacteria. Did FDA in its 9 years or 8 years they have had this petition find any science to justify these delays?

Dr. SUNDLOF. Again, the finding that irradiation does produce this cancer-causing substance, furans in some foods, is one of the things that has prevented us from moving forward, and I don't be-

lieve that information was available to those international organizations when they did make their decision.

Mr. STUPAK. Are there furans in leafy greens?

Dr. SUNDLOF. My information that I have indicates that irradiation of leafy greens at the rate that they would normally be irradiated would create minimal furans, so it would be very, very small.

Mr. STUPAK. So there would be no health risk?

Dr. SUNDLOF. So that is the direction we are proceeding, yes.

Mr. STUPAK. Well, if there is no health risk then why not approve the petition then?

Dr. SUNDLOF. Again, Mr. Chairman, we are working on it. There are a lot of administrative hurdles that we have to cross.

Mr. STUPAK. Yes, 9 years worth. Let me ask you this one. Canada and Japan have repeatedly found that seafood exports from Vietnam have tested positive for banned antibiotics. We have been told that every major importing country has found repeated shipments of Vietnamese shrimp tainted with banned antibiotics. It came up at our last hearing 2 weeks ago. We are also told that the FDA has known about the problem since at least 2003, but has yet to issue an import alert regarding Vietnamese shrimp imports. Is shrimp from Vietnam a problem? If so, why don't we have a Vietnamese shrimp import alert?

Dr. SUNDLOF. Mr. Chairman, we do analyze shrimp coming from Vietnam and other Asian countries. I think we have taken action in the past on Vietnamese fish, especially catfish, I know. I am not sure about the shrimp at this point but——

Mr. STUPAK. Could you get back with us on that?

Dr. SUNDLOF. We can certainly get back with you on that.

Mr. STUPAK. I mean the last testimony is we get Pakistani shrimp that is rejected in Europe, it comes here. They don't export anything here but in the last couple months they have done 165,000 pounds and it has got fungi and bacteria and that is why it is rejected in the EU, but we seem to have it here and the same with Vietnamese shrimp. As soon as it gets pushed out of another country, it seems to be dumped here because we are not checking for it. And there is no import alert around it even though we know the problems existed since 2003.

Dr. SUNDLOF. I do know that we have been testing imported shrimp and other seafood products from a variety of countries, and we have not seen an increase in the residues of those drugs. There hasn't been—you know, over the years, there has not been a spike. We don't see that so the——

Mr. STUPAK. But the bacteria found there is a health concern, is it not?

Dr. SUNDLOF. Bacteria?

Mr. STUPAK. Yes.

Dr. SUNDLOF. Bacteria certainly is, yes.

Mr. STUPAK. Let me ask you this. During the last hearing on February 26, a witness testified that in June, 2006, former Director of the Center for Food Safety and Applied Nutrition, Dr. Robert Brackett, stated that the FDA did not consider pesticide residues in food a serious matter and would no longer monitor them. As the new director of the Center for Food Safety and Applied Nutrition,

do you believe pesticide residue in food is a serious problem, and will the FDA monitor them under your direction?

Dr. SUNDLOF. Well, we certainly will monitor them, and we look at pesticide residues in light of all of the things that we consider to be risks associated with foods, and we try to prioritize. We normally analyze between 4,000 and 6,000 imported and domestic products per year for pesticides so it is not like we are not doing it. We are doing about between 4,000 and 6,000 pesticide analyses per year.

Mr. STUPAK. So which ones are most harmful of the analysis you have been doing? Which ones should the American people be on the lookout for on the pesticides and the amounts that are of concern?

Dr. SUNDLOF. Well, let me just say that 93 percent of the pesticides that we are finding are not because they are—we don't know if they represent a safety hazard. We think they probably are minimal. We don't have tolerances for them in the United States so any amount that we find would be a violation of our laws, and that is 93 percent of them so it is difficult to say which are the most important from a hazardous point of view but we do—when we do a screen we screen for over 300 different pesticides, and any one of those that is determined to be violative, we can take action. We have import alerts on, for instance, Dominican Republic produce right now because of pesticides.

Mr. STUPAK. Let me ask you this. At our last hearing on February 26, the CEO of a private lab that tests food under the import alert told the committee that we, and we already learned this from testimony last summer, that labs, private labs, will discard bad results at the request of the importer and the same private lab will keep testing the product until a positive result is obtained or the importer will hire another lab to test the product until a positive result is obtained. You were advised by our staff to review this testimony, were you not?

Dr. SUNDLOF. I don't know.

Mr. STUPAK. OK. Did you ever review that testimony?

Dr. SUNDLOF. I don't know if we did or not.

Mr. STUPAK. Do you realize that is a problem that if you put an import alert they go to a lab that will give them the results they want and then it comes in?

Dr. SUNDLOF. I do recognize that. I do recognize that that is an issue, and we can get back to you on that, Mr. Chairman.

Mr. STUPAK. OK. We have legislation moving on food safety. We are going to make that a requirement. Don't you think all lab tests if there is an import alert, if I am a private lab, I test whether it is a positive test or a negative test, you should have access to it, you should have——

Dr. SUNDLOF. We would like to have access to that.

Mr. STUPAK. So you would like to have that authority then?

Dr. SUNDLOF. We would like to have the information. Whether it requires legislation or not—it would be nice if we had the information from——

Mr. STUPAK. Having the information is one thing. Doing something about it is another thing. I mean just giving you the information isn't going to do anything. If you get a negative test, you can't lift the import alert, right?

Dr. SUNDLOF. If we get a negative—the way the import alert works is that if a company provides us with documented evidence that they no longer——

Mr. STUPAK. Had the problem.

Dr. SUNDLOF. Then they can——

Mr. STUPAK. But you don't know how many tests they take before they get one that shows that or which batch they are taking it from, correct?

Dr. SUNDLOF. That I don't know.

Mr. STUPAK. Wouldn't it be like in drugs, wouldn't it be better to get all the tests so you can make a determination whether or not this batch of food or shrimp from Vietnam is actually safe for human consumption, not just the ones that the private labs want to give you?

Dr. SUNDLOF. We would like to have as much information as we can get.

Mr. STUPAK. Thank you. Mr. Shimkus has some questions.

Mr. SHIMKUS. Mr. Raymond, would the USDA provide to this committee all the footage of films that you have on Westland/Hallmark?

Dr. RAYMOND. Yes, we would be glad to.

Mr. SHIMKUS. Dr. Sundlof, what is the risk of BSE from non-ambulatory cattle in the meat supply?

Dr. SUNDLOF. Well, in the United States——

Mr. SHIMKUS. In the United States.

Dr. SUNDLOF. In the United States, as Dr. Raymond said, it is very, very small testing.

Mr. SHIMKUS. What is a good word for very, very small?

Dr. SUNDLOF. Well, the phrase that has been used is vanishingly small but——

Mr. SHIMKUS. Vanishingly small.

Dr. SUNDLOF. Vanishingly small.

Mr. SHIMKUS. Percentage wise on a scale of 1 to 100, what would be vanishingly small? The point it, and I don't want to be trivial, but I want to—in 0 to 100 using decimals, what is vanishingly small?

Dr. SUNDLOF. Let me just say that I can't answer the question exactly but let me give you an example of how I believe USDA APHIS, Animal Plant Health Inspection Service, set up their survey in such a way that they would be able to detect one cow in 10 million. OK. They actually sampled well beyond what they had originally set out to do so rather than a couple hundred thousand, they sampled almost three-quarters of a million and they found two animals. Those animals were born before the 1996 feed ban. It implies that the number is somewhere below 1 in 10 million. So that is as close as I can get, and I would defer to Dr. Raymond if he has better numbers.

Dr. RAYMOND. I am sorry. I was trying to get myself out of a hole that I just dug.

Mr. SHIMKUS. I was thinking you might have got yourself in a hole but I will let you try to dig out when I——

Dr. RAYMOND. You are talking about how much we——

Mr. SHIMKUS. Why don't you let me just go, and I got some questions that follow up on this line anyway. It is really yours to an-

swer, Dr. Raymond, but it deals with BSE. Is there a postmortem testing for BSE? Dr. Sundlof, do you know? I know the testing is done by you all, but I want to ask the expert here.

Dr. SUNDLOF. My understanding is that postmortem testing is done when there is a suspect animal but not as a routine method.

Mr. SHIMKUS. Dr. Raymond.

Dr. RAYMOND. It is all postmortem because what we are doing is looking at the brains of these cows. We don't test them in the plant. There is no instantaneous test in the plant but animals that present to this particular plant and any other plant that are wobbly or appear to have central nervous system diseases are going to be sampled, and a sample of the downers are going to also be sampled so they are going to be tested. We are still testing 40,000 high risk cattle a year in this country.

Mr. SHIMKUS. And the result of the testing so far?

Dr. RAYMOND. Just the two animals since the enhanced surveillance started. The enhanced surveillance stopped——

Mr. SHIMKUS. They were born prior to——

Dr. RAYMOND. They were all born prior to the feed ban going into effect.

Mr. SHIMKUS. Post that time, none?

Dr. RAYMOND. No animals born after the feed ban have been found to have BSE in this country.

Mr. SHIMKUS. In this country. Any of these two in Hallmark/Westland plant?

Dr. RAYMOND. No. The two that we are talking about were downers on the farm. They were not even at a processing plant or a slaughter plant.

Mr. SHIMKUS. So they were no challenge to the food supply?

Dr. RAYMOND. The two that we have found since the first one went down in the State of Washington were on farm animals.

Mr. SHIMKUS. You went through the classes, so for the processing facility what is their response class 2 versus a class 3 recall? What would be the difference or is there?

Dr. RAYMOND. There is a difference. There is a difference between a 1 and a 2 and a 3 because of the severity of the risk, the threat to the American public.

Mr. SHIMKUS. And 2 is—I mean you know these. Can you restate 2 for me?

Dr. RAYMOND. A remote probability of adverse health consequences. If it is a class 1, we are going to do everything we can as quickly as we can to get all that product out of commerce and to alert the American public. A class 2 we are going to do the same thing but when you are dealing with a recall as big as this one it takes longer to get that product out and we have to use our resources to go out and verify the product has been removed. And we may be able to verify it a little quicker as a class 1.

Mr. SHIMKUS. My challenge is this, that I have already gone through the chain of command concerns that I have, the chain of custody issue, which I am not sure we understand yet. And then point two, if BSE is vanishingly remote, class 2 versus class 3, 1 in 10 million. Vanishingly remote, I can't quantify that.

Dr. RAYMOND. If we could say zero risk, we would have done a class 3. We cannot say zero risk. Those regs were put into place

in January of 2004 to mitigate the exposure, the risk of exposure to BSE for the American consuming public, and each one of those regulations is important. Some are more important than others. I would state to you that the SRM removal is absolutely the Number 1 most important thing we do to protect human health. The feed ban is the Number 1 thing we do to protect animal health. Those two together give us good safety but we also man mechanical separation of meat in cattle 30 months and over. We also ban downer cattle from entering the food supply. They are part of the interlocking steps that we have. And any time one of those steps is violated, we are going to have to take action.

Mr. SHIMKUS. If you would have done a class 3 to this facility, tell me the difference.

Dr. RAYMOND. It is still a recall. A recall is a recall.

Mr. SHIMKUS. So there is no difference?

Dr. RAYMOND. Not really. A sense of urgency within the department maybe or within the consuming public but a recall is a recall.

Mr. SHIMKUS. Is there any alternatives?

Dr. RAYMOND. They produce this product in non-compliance with our regulations and therefore by definition it becomes unfit for human consumption.

Mr. SHIMKUS. And I asked this earlier, of the facilities that were closed, they have reopened so Westland/Hallmark would have—what would they have to do to reopen?

Dr. RAYMOND. They would have to, A, assure us that they have steps in place that humane handling will be guaranteed, and that what happened with the humane handling won't happen again, and then they have to address the issue of the violation of the compliance with the laws and give us the things that have been into place to make sure that they are in compliance with all of our regulations.

Mr. SHIMKUS. You know, I guess the concern is we get the inhumane handling part. We understand that. The concern is that we want to make sure that what you did in the recall was based upon a concern of health and safety of the food supply versus using that process—there are other things to do to address inhumane handling than a class 2 or class 3 recall if the vanishingly small risk, which is 1 in 10 million. That is what a lot of us will struggle with, that the process was used—there are probably other legal aspects to be able to go after people who have a process by which there is inhumane treatment. My concern is that the health and safety of the food supply and that we don't use that as an excuse to attack people for being inhumane. There are other rules and regulations and laws that we can then enact.

Dr. RAYMOND. If it had just been inhumane handling, I have no doubt that that plant would be up working slaughtering animals today and processing them, but it was more than just inhumane handling. Our investigation showed that they produced a product in violation of our regulations.

Mr. SHIMKUS. One last question. Why didn't you show them the video when they asked for it?

Dr. RAYMOND. At that particular point in time when he asked, we were trying to determine how much of this is going to have to be kept confidential because of the ongoing violation. We were try-

ing to figure out a way to get him to be able to see it, but he never asked us a second time. I do believe some of his plant management did see it when we talked to them about recall. They had seen the 4-minute video.

Mr. SHIMKUS. I think there is a hole in the debate when you are talking about the immediate health and safety of the food supply, you are telling a person you are going to close them down. You probably owed it to him if he asked for the video to show him the video. And I will yield back my time.

Mr. STUPAK. But there was no reason why Mr. Mendell couldn't go online like the rest of America and viewed it online, right?

Dr. RAYMOND. No.

Mr. STUPAK. A lot of us are glad you did the recall. It was a clear violation. We don't want downer cows in our food supply so I think the USDA acted appropriately. Let me ask you this though, because—just a couple quick questions if I may—because I want to go back to carbon monoxide, Dr. Raymond. Target sent a formal letter to USDA asking to approve a label to alert consumers that packaging certain meat products that they would sell, Target would sell, are packaged in an atmosphere containing carbon monoxide. USDA did not approve this label, thereby essentially forbidding Target from telling the truth about its products to consumers. Is that true?

Dr. RAYMOND. For the record, I would like to read the letter, a portion of the letter, that was sent to us.

Mr. STUPAK. And can you provide it for the committee after you read it?

Dr. RAYMOND. Absolutely.

Mr. STUPAK. OK.

Dr. RAYMOND. "Target requests direction as to how best to submit information required in 9 C.F.R. 317.4 for the sketch labeling and for the FSIS form application for approval of labels, markings and devices." The letter—they asked us for direction twice, and they start out the letter in the first sentence says we are sending you this letter to request direction from FSIS. They didn't send us a label.

Mr. STUPAK. I see.

Dr. RAYMOND. And we provided a response to them for the direction. We have not heard back from them.

Mr. STUPAK. Could Target without USDA approval put on their meat packaging that the meat was packaged using carbon monoxide, color is not an accurate indicator of freshness, refer to use or freeze by date? Could they do that or do they need your approval to say this meat was packaged using carbon monoxide?

Dr. RAYMOND. All labels need our approval.

Mr. STUPAK. OK. Kyle, put up that sign. Were you here when we showed that sign earlier? I think there might be a copy right there on the desk. See right in front of you, Dr. Raymond, as you direct yourself towards the dais here. It is right there. Could in the meat area where Target sells their meat, could they put in there our fresh meat and seafood set standards, and basically it says we do not use carbon monoxide. Can they do that, just put a sign up?

Dr. RAYMOND. As long as it is truthful and not misleading, they can.

Mr. STUPAK. They don't need your permission to put a little sign up?

Dr. RAYMOND. As long as it is truthful and not misleading.

Mr. STUPAK. But if they put it on the label of that meat right there then they have to have your approval?

Dr. RAYMOND. That label has met our approval, yes, sir.

Mr. STUPAK. Right. Right. OK. So would you approve a label then which would say this meat is packaged using carbon monoxide, color is not an accurate indicator of freshness, refer to use or freeze by date? Would the USDA have a problem with that?

Dr. RAYMOND. I am not going to answer that today for you, sir, because I would want to see the whole label and we are making an assumption here. I would be glad to have our labeling team take a look at that request and get them an answer as quickly as we can.

Mr. STUPAK. Well, what I just read you is already used. Basically I think you have already approved, USDA has approved, "color is not an accurate indicator of freshness, refer to use or freeze by date," that has been approved by USDA.

Dr. RAYMOND. That language evidently has.

Mr. STUPAK. Right.

Dr. RAYMOND. If you are reading it, and I am sure it has. But, if I might, it could be in little teeny tiny letters. That is why we would have to see the whole label.

Mr. STUPAK. So your rejection is just—they are asking for guidance. You are saying basically show us what you want to put on your label.

Dr. RAYMOND. Exactly.

Mr. STUPAK. OK. So due diligence sort of fell apart, not on USDA part but on Target's part, is it fair to say?

Dr. RAYMOND. We responded to them in January and have not heard back from them since.

Mr. STUPAK. OK. And get us a copy of that letter there that you read from back to Target and we will make a copy of it. OK. They just informed me they have a copy of it. Mr. Shimkus, anything further?

Mr. SHIMKUS. Real briefly. You may not know the answer. Where are the cows, the spent dairy cows that used to go to Westland/Hallmark, where are they going? Do we know?

Dr. RAYMOND. No, I don't know.

Mr. SHIMKUS. Last question for you, Dr. Raymond. When you did your interviews based upon the receipt of this information, and you did interviews, did you interview the undercover Humane Society operative? Was that part of——

Dr. RAYMOND. Yes, it was, sir. Could I just before we go off of this just for the record because I did misspeak, any of the videotapes that we have that are on our Web page, of course we will share with you, but there have been some that the OIG perhaps has subpoenaed and obviously I cannot share theirs with you, so I just wanted to clarify that if I might.

Mr. SHIMKUS. Yes, I think we are interested in—unless it is any of those that are subject to the parameters you just mentioned. If there were videos that you would not show to Mr. Mendell, we

would like to see those unless those are the ones that are under subpoena or whatever.

Dr. RAYMOND. I assure you that I will talk to my legal folks and we will share with you everything I can share with you.

Mr. SHIMKUS. I am fine, Mr. Chairman.

Mr. STUPAK. Thank you. That concludes questioning. I want to thank all the witnesses for coming today, and thank you for your testimony. I ask unanimous consent that the hearing record will remain open for 30 days for additional questions for the record. Without objection, the record will remain open. I ask unanimous consent that the contents of our document binder be entered in the record. Without objection, the documents will be entered in the record. That concludes our hearing. Without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 4:50 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. GENE GREEN

Mr. Chairman, thank you for holding this hearing today on the Nation's food supply. I think it is important that we continue to have these hearings to address the issue food safety in the US.

This is the sixth hearing this committee has held on the issue of food safety and regulatory failure. These hearings have continuously highlighted the fact that the FDA and industry need to do more to make sure our food is safe to eat.

Each year in the US there are approximately, 76 million cases of foodborne illness and in the past year there have been numerous high profile food product recalls involving meat, fish, and vegetables. Today we will focus primarily on the safety of our meat and poultry supply.

The hearing today focuses on the need of the FDA and USDA to improve their food inspection system. I believe that many of the outbreaks that have recently occurred can and have been directly linked to a poor inspection system.

During these hearings on food safety, I have spoken many times of the need for more FDA inspectors at our ports. I represent the Port of Houston and I actually spent one day on the docks as they unloaded cargo and saw how the products are inspected.

It is clear to me, after observing activity at the Port of Houston and through these hearings, that the FDA and the USDA do not have enough inspectors protect our food supply.

If the FDA needs to hire third party inspectors or partner with another agency like the Department of Agriculture, then the FDA should do so to ensure product safety. However, as this hearing will show today, even though the USDA has third party inspectors, there are not enough inspectors to ensure food safety.

It is our responsibility to make sure that the FDA and the USDA have the resources they need to protect us from contaminated food products. We can't point out the problem without offering some solution as well.

If we need to provide more funding to allow the FDA and the USDA to protect our food supply then we should do just that. Consumers should be able to purchase food without worrying about botulism, E. coli, salmonella, or pesticides in their food.

The Westland/Hallmark beef recall, the largest food recall in the US, is an example of what our food inspection system lacks and how the lack of proper inspection directly affects the most vulnerable members of the population- children.

Westland/Hallmark was not consulting with USDA on downer cattle and consequently, this diseased beef entered the supply chain. Some of this recalled beef was supplied to schools in my district including Houston Independent School District and Pasadena School District.

The blatant disregard for proper handling of cattle and allowing the diseased cattle to enter the food supply highlights just how little regulation is actually in place at these food plants.

Clearly, this is a problem that isn't improving on its own and is only getting worse in my opinion.

Thank you, Mr. Chairman for holding this hearing and I want to thank our witnesses for appearing before the committee today. I yield back my time.

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

By signing below, I understand all policies and procedures that involve the Humane Handling and Harvesting of cattle (both ambulatory and non-ambulatory) at Westland/Hallmark Meat Company (WHMC). I have been instructed and trained regarding my job assignment(s) as documented in our written program.

I also understand that if I have any questions regarding the strict requirements of this program with regards to my assigned job(s) or that of others, I have been instructed and understand fully that I am to notify my direct Supervisor immediately.

WESTLAND/HALLMARK MEAT COMPANY

Sean Thomas — 10-8-07
Employee's Printed Name and Signature — Date

Jose Gustavo Mata — 10-8-07
Trainer's Name and Signature — Date

TRADE SECRET

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Sean Thomas Nov 12 / 07
Employee's Printed Name and Signature Date

Jose Gustavo Mendoza 11/7/07
Trainer's Name and Signature Date

TRADE SECRET

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

ACCOUNTS FROM HSUS INVESTIGATOR AT HALLMARK/WESTLAND MEATING COMPANY

1. I am employed as an investigator with The Humane Society of the United States.

2. Between October 3 and November 14 2007 I was employed as a pen worker for Hallmark Meat Packing Company which supplies beef to Westland Meat Company, Inc. My duties included unloading cattle from livestock trailers, handling cattle, driving cattle into the kill chute for slaughter, and stunning cattle prior to slaughter.

3. During my 6 weeks at Hallmark I witnessed and documented acts of extreme cruelty to cattle who were too sick or injured to stand up or walk to slaughter on their own power. I observed these illegal and inhumane animal handling practices on a daily basis.

4. I video-recorded numerous instances where animals too sick or injured to walk on their own, were tortured until they rose to their feet, and once they stood they were shocked and/or held by their tails to keep them up and moving into the chute to be slaughtered for human consumption.

5. I video-recorded a cow collapsing in the chute leading to the kill box. This cow never stood up again. She was shocked extensively, then shot in the head and dragged into the kill box by a chain attached to her neck.

6. On another instance I video-recorded a Jersey cow collapsing in the chute on the way to the kill box. Workers shock her and lift her by her tail to get her into the box. One worker holds her tail while the other shocks her face and then sides to keep her moving into the plant.

7. I video-recorded two workers holding up a cow that can not walk on her own. A hotshot is used continuously to get the cow up and then they hold her by her tail and move her up the chute into the kill box. Another worker grasps the tail while standing alongside the chute to keep the cow upright. As soon as the cow enters the kill box the workers let go of her and she collapses. The door is quickly slammed shut to keep her from falling back into the chute. The workers then proceed back to the alley where another downed cow is lying and one shocks her while the others stand behind her pushing to get her to stand. Workers continue to shock the cow along her side and then her face causing her to vocalize. Eventually they push her to her feet and walk her up the chute. Workers hold her up and another shocks her from alongside the chute. They put her into the kill box and quickly shut the door.

8. I video-recorded the pen manager shocking a down cow in the covered pen outside the crowd pen; he uses a pocket sized hotshot to apply electricity to her face and body. He then sprays water from a high pressure hose into her mouth and nose causing the cow to stand while workers hold her tail and walk her up to the kill box while continuously shocking her to keep her on her feet and moving.

9. I video-recorded the pen manager and a worker approach a cow that has collapsed in the alley leading to the chute. She is unable to walk to the chute. The manager shocks the cow while another worker lifts her by her tail and then walks her up the chute. Another worker stands above the chute grasping the cows tail so that she cannot collapse again. The hotshot is continuously applied to keep the cow upright and moving.

10. I video-recorded workers shocking a large cow with an electric cattle prod and dragging her from a truck by a chain attached to a forklift operated by an experienced worker. The pen manager then drags the cow some more and then rams her into the pen with the forklift trying over and over to get her to stand by using the forklift until she is held up by workers and is put in the alley in line for slaughter.

11. I video-recorded an experienced worker pushing a cow down the stairs inside a truck instead of euthanizing her. The cow then collapses on top of a forklift at the truck's rear exit, which the worker moves, causing the cow to fall several feet to the pavement. He then pushes and drops her with the lift until she is placed in a pen with other healthy cows, blood is running from her vagina and rectum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

APR 17 2008

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the March 12, 2008, hearing before the Subcommittee on Oversight and Investigations entitled "Regulatory Failure: Must America Live with Unsafe Food?" This letter provides a response for the record to questions raised during the hearing.

We have repeated the questions in bold below, followed by the Agency's response.

The Honorable Bart Stupak

We have heard previous testimony about shrimp from Vietnam being contaminated with banned antibiotics. Is Vietnamese shrimp a problem? If so, why don't we have an import alert?

The use of unapproved animal drugs in aquaculture is found not only in Vietnam but in other Asian countries as well. FDA has, since December 2007, increased its sampling of seafood for unapproved animal drug residue across twenty countries, including Vietnam. Concerning Vietnamese shrimp, two samples have been found to contain unapproved antibiotics under this increased sampling program. FDA will continue to work with the companies and the government of Vietnam to address this issue.

Although unapproved animal drug residues in shrimp and other aquaculture products have decreased since 2005, the Agency continues to find residues of chloramphenicol in crab meat. FDA does have an Import Alert (IA #16-124) for "Detention without physical examination of aquaculture seafood products due to unapproved drugs," instituted in 2002, which is still in effect and includes seafood processors from Vietnam. FDA also has a separate Import Alert for crab meat contaminated with chloramphenicol (IA #16-127), which includes Vietnamese firms.

FDA has worked closely with the seafood regulator in Vietnam, National Fisheries Quality Assurance and Veterinary Directorate (NAFIQAVED), to deal with the issue of unapproved

animal drug residues in its seafood products. FDA has addressed this issue proactively with Vietnam over the last few years and has seen a steady decrease in violative seafood products.

As a result, the NAFIQAVED committed to developing and implementing a program of short-term and long-term actions to address the problem of the application of unapproved animal drugs on farmed fish. This included temporarily testing all shipments of seafood products for chloramphenicol, nitrofurans, malachite green, and fluoroquinolones intended for export to the U.S. FDA conducted training on Good Aquaculture Practices (GAqP) with Vietnam government officials and the seafood industry in November 2006 as part of this process. FDA officials also met with NAFIQAVED in December 2007 to enhance the exchange of information and to enhance our understanding of their structure and organization.

Health and Human Services Secretary Michael O. Leavitt is visiting Vietnam April 14- 18, 2008, and seafood safety is one of the issues discussed with government officials. FDA participated in the delegation with the express purpose of meeting with NAFIQAVED to continue our dialogue. FDA is tentatively scheduled to visit Vietnam in September 2008 to further evaluate Vietnam's control measures for animal drug residues in aquaculture products, to assess implementation of GAqP principles on farms, and to inspect firms that ship these products to the U.S.

Thank you again for the opportunity to provide testimony at the hearing. We look forward to continuing to work with you and your staff on these important food safety issues.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

[redacted]t for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether [redacted]ments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public [redacted]g burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching [redacted] data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this [redacted] estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

US Department of Agriculture
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☐ Food Safety ☒ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
12/08/2005	0017-2005-4174	00336 M / 1

4. TO (Name and Title)	5. PERSONNEL NOTIFIED
Stanley Mendell, Plant Manager- Processing/Grinding	Stanley Mendell, Pablo Salas

6. RELEVANT REGULATION(S)
313.1(a); 313.2(b); 313.15(b)(iii)

7. SECTION/PAGE OF EST. PROCEDURE PLAN	HACCP	SSOP	OTHER
			N/A

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
04C02	PRODUCT - Protocol

10. DESCRIPTION OF NONCOMPLIANCE

During a Humane Handling visit of the facilities at Hallmark Meat Packing, EST. 336 by Dr. Susan Knox, D.V.M.S., Alameda District Office, the following noncompliance were observed: 1) wooden planks along the main drive from pen #10 through pen #15 with nail heads (too many to count) sticking out, and it has rough surface. It was also noted that clamp of hairs were seen attached to the surface of the wooden planks. 2) By pen # 12 two pieces of broken wooden boards were also noticed. 3) In pen #13 metal strip (divider) broken off, it was protruding with pretty sharp edges that could cause injury to the animals. It is about 1-1/2 to 2 inches in depth. 4) drains (5 inches in diameter) along the main drive by pens #2A through #4A without drain covers. 5) Opposite pen #10 there was a big hole on cement and between pens #A1 and #A2 the cement was cracked and broken about a foot to a feet and a half where an animal's foot could get caught. 6) On pen # 15 water trough is empty and there were animals in the pen. 7) Too much electric prodding causing animals to get more excited while being driven towards the stunning box. Out of 100 animals observed, 33 were prodded and out of the 33, 22 animals required multiple prodding to get then into the knocking box. All of the above could cause unnecessary pin and suffering to the animals. This document is written as a notification that your failure to comply with the regulatory requirement(s) of the Humane Slaughter Act of 1978 could result in additional regulatory or administrative actions including suspension.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
Gabriel Gurango 12/09/05

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE (Immediate action(s)):
SEE ATTACHMENT.

13. PLANT MANAGEMENT RESPONSE (further planned action(s)):
SEE ATTACHMENT.

This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT
15. DATE 12-29-2005

16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
17. DATE

FSIS FORM 5400-4 (7/98)
Replaces FSIS Form 5400-4 (9/97), which may be used until exhausted (7/98)

DISTRIBUTION: Original & 1 Copy to Establishment, 1 Copy to Inspector
Page 1 of 1

Westland /Hallmark Meat Company

ESTABLISHMENT REJOINDER TO NR-17-2005-4174

12. PLANT MANAGEMENT RESPONSE *(Immediate action(s)):*

1. The wooden planks along the main drive from pens #10 through #15 with nail heads sticking out were removed and the rough surface was eliminated with new wooden planks.
2. There was two (2) pieces of broken wooden boards by pen #12 which were replaced with new wooden boards.
3. The metal strip divider in pen #13 which was protruding with sharp edges was removed.
4. Drain covers by pens #2A through #4A had covers placed on them.
5. A hole that was observed opposite pen #10 was filled with cement and the cement between #1A and #A2 was repaired with cement eliminating the cited cracks.
6. The water trough at pen #15 was filled immediately with water.
7. Re-training of corral personnel was immediately implemented to significantly truncate the amount of electrical prodding.

(THE PICTURES ATTACHED TO THIS NR REJOINDER EVINCES THAT ALL CORRECTIONS HAVE BEEN COMPLETED IN A TIMELY MANNER)

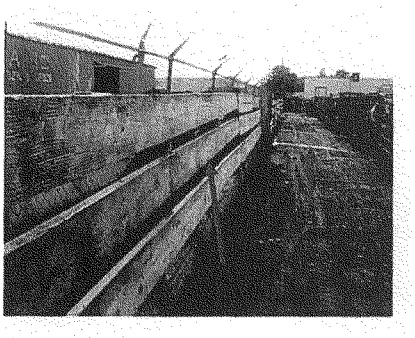
13. PLANT MANAGEMENT RESPONSE *(further planned action(s)):*

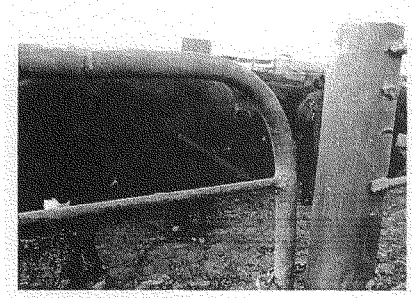
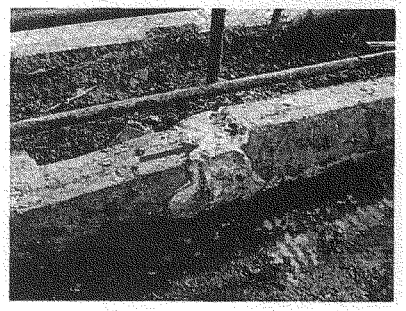
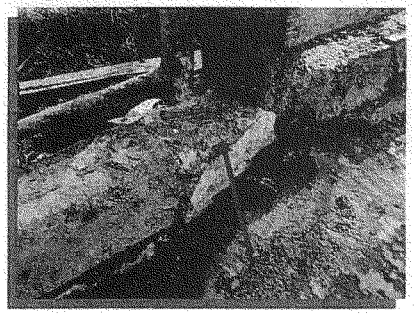
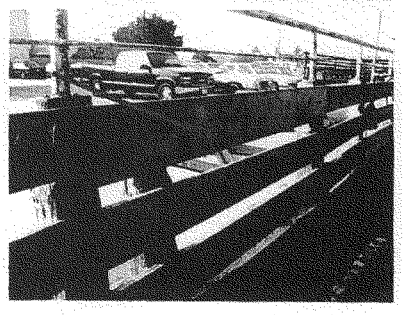
Further planned preventive measures regarding items 1 through 7 have been put into action in order to eschew similar incidents from occurring again as was documented in NR 17-2005-4174.

Increased corral maintenance surveillance by both the maintenance department and corral personnel was immediately put into place which will clearly identify and correct in a timely manner any area of the corrals infrastructure that may cause injury to the livestock. In addition increased training of corral personnel has been put into place and will continue to be provided in order to truncate the use of electric prodding on livestock. All feed and water troughs will be visually checked on a daily basis to ensure that there is sufficient supply for the livestock.

Westland/Hallmark Meat Company (WHMC) is steadfastly committed to abiding in full to all regulatory requirements regarding the Humane Slaughter Act of 1978. WHMC will continue to train company personnel on the importance of the humane handling of livestock and will continue to monitor the corrals in order to ensure that there are no hazards to the livestock.

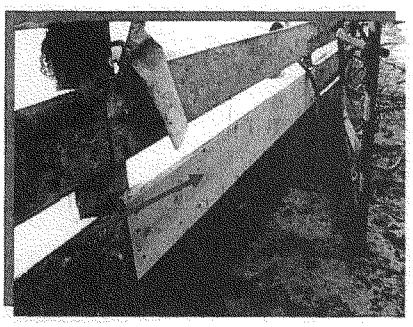
WESTLAND /HALLMARK MEAT COMPANY ESTABLISHMENT #336

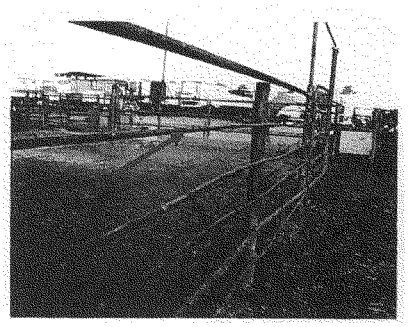


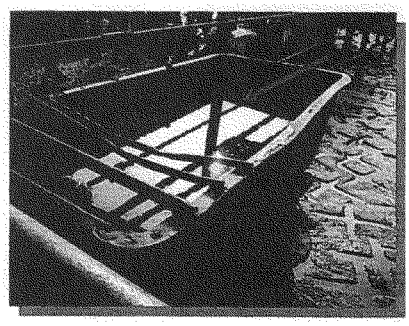





13677 YORBA AVENUE CHINO CALIFORNIA 91710

WESTLAND /HALLMARK MEAT COMPANY ESTABLISHMENT #336







Skip Navigation

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21 CFR 7.3 (m) Recall classification

- Class I is a situation in which there is a reasonable probability that the use of or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II is a situation in which use of or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III is a situation in which use of or exposure to, a violative product is not likely to cause adverse health consequences.

Text Only Version

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
MAJORITY STAFF
MARCH 2008

FDA and Fresh Spinach Safety

PREPARED FOR
CHAIRMAN HENRY A. WAXMAN
CHAIRWOMAN ROSA DELAURO

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EXECUTIVE SUMMARY

In September 2006, the United States suffered a major outbreak of *E. coli* O157:H7, causing hundreds of reported injuries and several deaths and resulting in a spinach recall. The outbreak ultimately was traced to packaged fresh spinach. This was not the first outbreak tied to fresh produce. There have been at least 20 outbreaks of *E. coli* O157:H7 in fresh spinach or lettuce in the past 12 years.

At the request of Rep. Henry A. Waxman and Rep. Rosa DeLauro, this report examines the Food and Drug Administration's efforts to protect the safety of packaged fresh spinach. As part of this investigation, the Committee requested and received inspection records for all FDA inspections of firms producing packaged fresh spinach from 2001 to 2007.

The FDA inspection records reveal:

- **Packaged fresh spinach facilities were inspected only once every 2.4 years, less than half of FDA's stated goals.** Frequent inspections are the cornerstone to the current safeguards for fresh produce and adequate resources are required for frequent inspections. FDA's performance goals state that 95% of high risk facilities like packaged fresh spinach facilities should be inspected at least once yearly. Over a seven-year period, FDA provided 199 inspection reports for 67 packaged fresh spinach facilities. This translates to an inspection rate of about one inspection of each facility every 2.4 years, less than half of FDA's stated goal.

- **FDA observed objectionable conditions during 41% of the packaged fresh spinach facility inspections.** Of the 199 inspections reviewed, 93 documented "objectionable conditions," the most common of which involved plant sanitation, plant construction, and worker sanitation. For example, more than 60% of the inspections with "objectionable conditions" revealed problems related to facility sanitation, such as inadequate restroom cleanliness or accumulations of litter.

- **Despite observing objectionable conditions in packaged fresh spinach facilities, FDA took no meaningful enforcement action.** FDA did not refer any of these inspections with objectionable conditions for further action by its own enforcement authorities. In one case, FDA did refer one inspection to the state for further action. FDA did not issue warning letters or pursue more aggressive steps such as seizures or injunctions.

- **FDA overlooked repeated violations.** In 38 cases, FDA observed repeated violations by packaged fresh spinach facilities but did nothing to force correction. Instead of taking enforcement action, FDA continued to request voluntary compliance after recording violations at each inspection. 14 of these repeat requests for voluntary compliance were for precisely the same violations.

- **FDA found repeated problems at multiple facilities operated by the firm implicated in the 2006 E. coli outbreak but took no enforcement actions.** The records show that in the years prior to the outbreak, FDA conducted multiple inspections of several packaged fresh spinach facilities operated by Natural Selection Food LLC and repeatedly found problematic conditions at a number of these facilities. According to the inspection records, however, FDA at no time required the firm to correct these conditions at any of its facilities, even after laboratory tests indicated the presence of microbial contamination at the exact site later implicated in the 2006 outbreak.

- **In eight cases, packaged fresh spinach facilities denied FDA inspectors access to records or other relevant material.** In eight instances, facilities prevented FDA inspectors from conducting a full review of the food safety practices. Under current law, FDA lacks the authority to compel production of firm records. On one occasion, inspectors were denied access to written records by the facility that was the site of the 2006 outbreak.

- **The scope of the FDA inspections appears too narrow to capture the sources of an E. coli outbreak.** The California Department of Health Services and the FDA performed a joint investigation into the causes of the 2006 spinach outbreak and found that the outbreak probably did not originate in the facilities that are inspected by FDA. Instead, the problem began outside the plants and most likely was due to contamination of the water outside of the plant by cattle feces, pig feces, or river water. FDA does not routinely inspect the fields except in outbreak investigations. In fact, none of the 199 Establishment Inspection Reports reviewed by Committee staff indicated that any observations of field conditions had taken place. Laboratory sampling can detect some microbial contaminations, but cannot prevent many outbreaks. The outdated statutory sanitation standard severely limits the scope of FDA's ability to adequately prevent many outbreaks.

The inspection reports provided to the Committee raise serious questions about the ability of FDA to protect the safety of fresh spinach and other fresh produce. It appears that FDA is inspecting high-risk facilities infrequently, failing to take vigorous enforcement action when it does inspect and identify violations, and not even inspecting the most probable sources of many outbreaks.

Inadequate funding and resources for food safety activities at FDA may contribute to the problems identified in this report. The Science Board, an independent FDA advisory committee, submitted a report to the FDA Commissioner in December 2007 that concluded: "FDA's ability to provide its basic food system inspection, enforcement and rulemaking functions is severely eroded, as is its ability to respond to outbreaks in a timely manner and to develop and keep pace with the new regulatory science needed to prevent future problems. ... [W]e can state unequivocally that the system cannot be fixed within available resources."

I. BACKGROUND

In the late summer and fall of 2006, 205 people were infected with a virulent strain of *E. coli* O157:H7 in connection with packaged fresh spinach. Reactions ranged from relatively mild to the most severe: 103 individuals were hospitalized, while three died from the infection.[1]

This was the 20th major outbreak of *E. coli* O157:H7 in fresh lettuce or spinach since 1995.[2] According to experts, there are a number of factors that are contributing to the growing incidence of fresh produce outbreaks. First, fresh-cut produce is the fastest growing segment of a fresh produce market that is growing overall, driven in part by the appeal of pre-made salads and packaged spinach among busy consumers.[3] Second, such foods often are consumed without cooking or other preparation, meaning that there is no routine "kill step" for foodborne contaminants such as *E. coli* or *salmonella*.[4] Third, food systems have grown more centralized in recent years, with food produced in a single region or even a single facility distributed to consumers throughout the country.[5] This nationwide distribution system means that once local outbreaks can now have nationwide reach, causing more illness and taking longer to detect and trace back to the source. Finally, some of the increase in fresh produce outbreaks may be due to changes in reporting.

To investigate these issues, Rep. Henry A. Waxman, Chair of the House Committee on Oversight and Government Reform, and Rep. Rosa DeLauro, Chair of the House Appropriations Subcommittee on Agriculture, requested inspection documents and data from FDA relating to its inspection of facilities producing packaged fresh spinach between January 1, 2001, and February 21, 2007.[6] In response to the Committee's request, FDA produced 199 Establishment Inspection Reports (EIRs) involving 67 facilities that produce packaged fresh spinach that were inspected during the specified six year period. These included EIRs for the facility in San Juan Bautista implicated in the spinach outbreak in Fall 2006.[7]

This report is based on an analysis of the EIRs. In preparing this report, Committee staff also consulted with food safety experts. These experts included a number of former FDA officials, such as William Hubbard, retired FDA Associate Commissioner for Policy and Planning from

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[1] California Department of Health Services and the U.S. Food and Drug Administration, *Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach* (Mar. 27, 2007).

[2] FDA, *Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce* (Nov. 4, 2005). According to this 2005 letter, 19 outbreaks of *E. coli O157:H7* in lettuce or spinach occurred from 1995 to 2005. The outbreak in 2006, therefore, was the 20th outbreak since 1995.

[3] Economic Research Service, USDA, *U.S. Fresh Produce Markets: Marketing Channels, Trade Practices, and Retail Pricing* (Sept. 22, 2003).

[4] FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (Mar. 2007).

[5] Economic Research Service, USDA, *U.S. Fresh Produce Markets: Marketing Channels, Trade Practices, and Retail Pricing* (Sept. 22, 2003).

[6] Letter from Chairman Henry A. Waxman and Chairwoman Rosa DeLauro to Commissioner Andrew C. Von Eschenbach (Feb. 22, 2007)(online at www.oversight.house.gov/story.asp?ID=1190).

[7] FDA, *FDA Announces Findings From Investigation of Foodborne E. coli 0157:H7 Outbreak in Spinach*, FDA News, (Sept. 29, 2006) (online at www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html).

1991-2005; Michael Taylor, former Deputy Commissioner for Policy at the FDA from 1991-1994 and Food Safety and Inspection Service Administrator from 1994-1996; and Leroy Gomez, retired Regional Food and Drug Director, Southwest Region.

II. FDA INSPECTION AND ENFORCEMENT PROCEDURES

Under the Federal Food, Drug and Cosmetic Act, any food that is "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" is deemed adulterated and its sale is prohibited.[8] To implement the Act's prohibition on the sale of adulterated or otherwise contaminated food, FDA has issued Good Manufacturing Practices (GMPs) for foods, including packaged fresh produce.[9] These GMPs, created in 1986, impose basic safety standards, including requirements for worker sanitation, plant construction, and plant cleanliness.[10] Though not specific to fresh produce, the GMPs provide the basis for FDA's authority with regard to fresh packaged spinach facility inspections.

Inspections are the mechanism for enforcement for food GMPs. According to FDA, with respect to food, "inspections and surveillance are the primary means of assuring the safety of marketed products. Consumers rely on the FDA to prevent dangerous and unreliable products from entering commerce."[11]

At the close of every inspection, FDA inspectors issue an EIR which details the production history and management of the firm, inspection findings, samples taken, and inspection conclusions. This EIR is submitted to a regional FDA district office after the inspection.[12]

In addition to the EIR, which is issued for all inspections, an inspector who observes "objectionable conditions" also must prepare a Form 483 to record such observations. Under FDA procedures, the Form 483 serves as the written notice to firms of any "objectionable conditions" that are found.[13]

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[8] 21 U.S.C. § 342; 21 U.S.C. § 331.

[9] 21 C.F.R. 110 (2006).

[10] *Id.*

[11] Office of Management, FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2007* (online at http://www.fda.gov/oc/oms/ofm/budget/2007/HTML/1Foods.htm).

[12] Office of Regulatory Affairs, FDA, *ORA Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (June 2007) (online at www.fda.gov/ora/inspect_ref/fmd/ fmd86.htm).

[13] *Id.* The Form 483 is used to notify a firm's management of significant objectionable conditions "when in the investigator's 'judgment' conditions or practices observed indicate that any food ... [has] been adulterated or [is] being prepared, packed, or held under conditions whereby [it] may become adulterated or rendered injurious to health."

As defined by FDA regulations, objectionable conditions are those that "indicate that the food [has] been adulterated or [is] being prepared, packed, or held under conditions whereby [it] may become adulterated or rendered injurious to health."[14]

Based on the EIR and the Form 483, FDA assigns an Inspection Conclusion for each inspection, designating the type of follow-up action indicated according to the following categories:

- No Action Indicated (NAI): No objectionable conditions or practices were found during the inspection or the objectionable conditions found do not justify further regulatory action.
- Voluntary Action Indicated (VAI): Objectionable conditions were found but the district office is not prepared to take or recommend any administrative or regulatory action. Any corrective action is left to the establishment to take voluntarily.
- Official Action Indicated (OAI): Regulatory or administrative sanctions will be recommended, including voluntary recalls where the district has decided conditions warrant either regulatory or administrative action. Such enforcement action may include a citation, a warning letter, or seizure. Additional enforcement action may also include fines for pesticide tolerance violations or criminal cases.
- Referred to State (RTS): Normally, only EIRs in which objectionable conditions were observed for which FDA either cannot or chooses not to take regulatory or administrative action are referred to states. The district office is obligated to maintain contact with the state to learn if action is taken.[15]

III. FRESH PRODUCE INSPECTIONS AND ENFORCEMENT FINDINGS

A. Objectionable Conditions

The EIRs provided to the Committee varied in format and language. While "objectionable conditions" was the most common classifying term, additional negative observations were also noted as "discussion with management," "deficiencies," or "concerns." In 199 of the EIRs

[14] Office of Regulatory Affairs, FDA, *Investigations Operations Manual*, Ch. 5 § 2.3.2 (Feb. 2007) (online at www.fda.gov/ora/inspect_ref/iom/ChapterText/5_2.html#5.2.3.2).

[15] Office of Regulatory Affairs, FDA, *Field Management Directive No. 86: Establishment Inspection Report Conclusion* (June 2007) (online at www.fda.gov/ora/inspect_ref/fmd/fmd86.htm); FDA, *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables, Draft Final Guidance* (Mar. 2007). Raw agricultural commodities are not subject to Current Good Manufacturing Practice requirements, but packaged fresh produce is considered processed food and therefore falls under Current Good Manufacturing Practice requirements under 21 C.F.R. § 110.

reviewed by Committee staff, 93 (47%) contained "objectionable conditions." Including the additional ways in which unsatisfactory conditions were noted, 116 (58%) EIRs contained negative observations. These records demonstrate potentially unsafe conditions at more than half of the spinach facilities inspected by FDA from 2001 to 2007.

The most common problem observed related to basic plant cleanliness: more than 60% of the inspections reporting "objectionable conditions" revealed problems related to facility sanitation, such as inadequate restroom cleanliness or accumulations of litter. The next most common problem identified was plant construction, cited in more than half of the violations. Observations in this area included findings that condensation had accumulated inside the plant, threatening to contaminate the food with water-borne microorganisms, and that plant design allowed for rodent infiltration, which might introduce filth or otherwise contaminate the food. The third major concern was worker sanitation, including issues such as uncovered hair, jewelry, or clothing, and poor hygiene practices. Worker sanitation concerns were raised in more than one tenth of the violations.

B. No Official Enforcement Action

FDA inspectors observed problems at many of the facilities inspected, but "objectionable conditions" were not referred for official action in any of the inspections reviewed. As shown in figure 1, FDA classified 117 of the EIRs as "no action indicated." 81 of the EIRs were classified as "voluntary action indicated" and one EIR was referred to a state for further action.[16] FDA did not classify a single case as OAI.[17]

Figure 1: FDA Inspections and Classification	
No Action Indicated	117
Voluntary Action Indicated	81
Official Action Indicated*	0
Referred to State	1
Total Number of Inspections	199

In an inspection conducted in September 2005, FDA found serious objectionable conditions at a Fresh Express facility. Inspectors observed spinach leaf pieces, carrot pieces, and salad residue on facility equipment, as well as an unidentifiable "scrapable" brown residue on at least four chutes and at least two product conveyor lines.[18] In addition, the broccoli conveyor, lined with broccoli flowerets, had a four inch tear through it. Finally, rust and condensation were seen on the beams over the scales and the salad line, and the ceiling panels were loose and cracked.[19]

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[16] FDA referred one case to the state of New Jersey, issued a warning letter to the firm after this referral. New Jersey District Office, FDA, *Establishment Inspection Report:* Seabrook Bros & Sons (May 19-22, 2006).

[17] The narrative of one EIR mentions a warning letter, but in documents provided to the Committee, the inspection was classified by FDA as VAI. In communications with the Committee, FDA indicated that the state in which this firm was located separately issued a warning letter to the firm. Detroit District Office, FDA. *Establishment Inspection Report:* All American Produce, Inc. (Jul. 23, 2002).

[18] San Francisco District Office, FDA, *Establishment Inspection Report:* Fresh Express Fresh Foods (Sept. 13-15, 2005).

[19] *Id.*

Based on these observations, FDA issued a Form 483 and classified the inspection as Voluntary Action Indicated.[20] Under a VAI classification, FDA may issue an untitled letter, request a regulatory meeting, or request a written response from the firm.[21] FDA took no such actions with regard to Fresh Express.

In fact, according to the records provided to the Committee, FDA took no such actions with respect to any packaged fresh spinach facility issued a VAI classification.

C. Repeat Observations and Classifications

As noted above, 81 of the 199 EIRs reviewed were classified by FDA as Voluntary Action Indicated, or VAI. Approximately 47% of these classifications (38) were repeat VAI classifications for a facility that had been designated as VAI in the previous inspection. 14 of these VAI classifications were due to the same objectionable observation made in the prior inspection. In the other 24 EIRs, the classification was based upon different objectionable observations.

One notable example of repeat observations involved the Yuma, Arizona, facility of Natural Selection Foods LLC. The Yuma facility was inspected five times between March 6, 2002, and February 6, 2006, by the Los Angeles FDA district office, receiving a VAI classification and a Form 483 at each inspection. Several repeat observations were reported over this four-year period, including indications that the facility failed to take effective measures to prevent extraneous materials from entering the food; failed to clean and maintain processing equipment; failed to ensure that condensation did not contaminate the product; and failed to review and verify plant records pertaining to sanitation.[22] Despite these repeated violations, FDA never initiated any enforcement action against Natural Selection Foods. In 2006, the San Juan Bautista facility of Natural Selection Foods was identified as the source of the 2006 *E. coli* O157:H7 outbreak in packaged fresh spinach.[23]

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[20] *Id.*

[21] Office of Regulatory Affairs, FDA, *ORA Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (June 2007) (online at www.fda.gov/ora/inspect_ref/ fmd/fmd86.htm).

[22] Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Mar. 6-7, 2002); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Jan. 8-9, 2003); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Feb. 27, 2004); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Dec. 8-9, 2004); Los Angeles District Office, FDA, *Establishment Inspection Report*: Natural Selection Foods LLC (Feb. 6-8, 2006).

[23] FDA, *FDA Announces Findings From Investigation of Foodborne E. coli 0157:H7 Outbreak in Spinach*, FDA News (Sept. 29, 2006) (online at www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html).

D. Laboratory Sampling

Laboratory sampling could reveal serious health threats such as microbial contamination by *E. coli* O157:H7. The staff analysis found that FDA tested product samples in only 41 of 199 inspections, just one-fifth of the total inspections. Even when presented with information indicating the presence of possible contamination, FDA neglected to collect product samples. Moreover, inspections rarely referenced sampling results from earlier inspections of the same facility. In only three of the 41 cases involving sampling were the results mentioned in the following inspection.

These findings are illustrated by the July 2001 inspection of the Natural Selection Foods facility in San Juan Bautista implicated in the 2006 spinach outbreak. The facility told FDA during the inspection that "a swab taken in a drain in the raw storage product room came back positive for *Listeria*" but that additional swab results were negative for these bacteria after a thorough cleaning. The FDA inspector did not collect samples at that inspection or at the next inspection in April 2002. FDA took samples only at a third inspection, in August 2002, over a year after learning of a potential contamination. These samples were positive, this time for a more dangerous type of *Listeria* that can cause meningitis and death in people with deficiencies in their immune system or stillbirths in pregnant women.[24] There is no evidence that after the positive sample in August 2002 — in four inspections from 2003 to 2005 — FDA again took samples at this facility. Nor did FDA mention these prior, multiple instances of microbial contamination in any of these four subsequent inspections.

E. Records Refusals During Inspections

In eight of the 199 EIRs reviewed, FDA inspectors reported that the facility being inspected refused to grant access to records. The most common items refused were facility records (e.g., food sampling and maintenance records) and consumer complaint files. Under current law FDA lacks the authority to compel access to such records.

One of the facilities that refused to grant access to records was the Natural Selection Foods facility in San Juan Bautista, California, the facility implicated in the 2006 spinach outbreak.[25] FDA inspectors at this site requested written procedures on recalls during two separate inspections, one in 2001 and one in 2002. The facility refused to provide access to these records during both inspections.[26]

A refusal also occurred during FDA's inspection of Fresh Express Fresh Foods in Salinas, California, in September 2005. In that inspection, the facility refused to allow inspectors to

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[24] FDA. *Bad Bug Book- Listeria monocytogenes* (online at www.cfsan.gov/~mow/chap6.html).

[25] California Department of Health Services and the U.S. Food and Drug Administration, *Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged* Spinach (Mar. 27, 2007).

[26] San Francisco District Office. FDA, *Establishment Inspection Report*: Natural Selection dba Earthbround Farms (Jul. 25-26, 2001); San Francisco District Office, FDA, *Establishment Inspection Report*: Natural Selection dba Earthbound Farms (Aug. 8-30, 2002).

review records pertaining to environmental sampling, final product testing, pest control, water sampling, and consumer complaints.[27]

F. Scope of FDA Inspections

In March 2007, the California Department of Health Services and FDA issued a report of a comprehensive investigation into the causes of the 2006 outbreak of *E. coli* O157:H7 in spinach. The investigators determined that the most likely source of introduction was in the field, an area FDA does not routinely inspect. The investigation found no obvious sources for introduction at the processing facility, but did find multiple factors in the facility that could have contributed to the spread of the pathogen, such as invalidated methods for testing wash water and incomplete records.

The causative *E. coli* DNA fingerprint was found in feces from nearby grazing cattle, feces from wild boars that had apparently gained access to the fields, and river water. The most likely route for this *E. coli* to contaminate the spinach was probably the contamination of water outside of the plant, either contamination of irrigation water or contamination of the water used to process the spinach, or both.

None of the 199 inspection reports reviewed by Committee staff contained any observations from practices in the fields. Instead, the FDA inspectors primarily examined the general sanitation and construction of the facilities themselves. The statutory sanitation standard that authorizes these inspections dates back to 1938 and does not provide clear authority to inspect the fields. Nor does this standard provide clear authority to require facilities to test product and water as they enter the plant for processing.

Laboratory sampling can detect some microbial contaminations, but as noted above, this testing is not currently adequate. Even a robust system of sampling would miss many bacterial contaminations since some diseases can be spread with just a few microbes. The outdated statutory sanitation standard for inspections severely limits the scope of FDA's ability to adequately prevent many outbreaks.

IV. CONCLUSION

The Committee staff review of inspection documents reveals that packaged fresh spinach facilities were inspected infrequently. Objectionable findings were common, but FDA took virtually no meaningful enforcement action, even after repeated violations. In some cases, FDA inspectors were not even granted access to records or other key materials at the facility. In

[27] San Francisco District Office, FDA, *Establishment Inspection Report*: Fresh Express Fresh Foods (Sept. 13-15, 2005).

addition, the system of FDA's inspections appear to be poorly targeted since the most likely source of the outbreak of *E. coli* in spinach appears to have originated in the fields, an area that FDA does not routinely inspect.

The problems identified in this report may in part derive from inadequate funding and resources for food safety activities at FDA. The Science Board, an independent FDA advisory committee, submitted a report to the FDA Commissioner in December 2007 that addressed FDA's capacity to protect the food supply. The Science Board concluded: "we can state unequivocally that the system cannot be fixed within available resources."[28] According to the report:

> FDA's ability to provide its basic food system inspection, enforcement and rulemaking functions is severely eroded, as is its ability to respond to outbreaks in a timely manner and to develop and keep pace with the new regulatory science needed to prevent future problems arising from both novel (prion disease, genetically modified organism) and traditional (resistant microbes, chemical contamination) sources. There is an appallingly low inspection rate: the FDA cannot sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products. During the past 35 years, the decrease in FDA funding for inspection of our food supply has forced FDA to impose a 78 percent reduction in food inspections, at a time the food industry has been rapidly expanding and food importation has exponentially increased. FDA estimates that, at most, it inspects food manufacturers once every 10 years, and cosmetic manufacturers even less frequently. The Agency conducts no inspections of retail food establishments or of food-producing farms.[29]

28 FDA Science Board. Supra note 28 at 53.

29 FDA Science Board. FDA Science and Mission at Risk: Report of the Subcommittee on Science and Technology, 21(Nov. 2007).

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

April 16, 2008

Mr. Steven E. Mendell
President
Hallmark/ Westland Meat Company
13677 Yorba Avenue
Chino, CA 91710

Dear Mr. Mendell:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, March 12, 2008, at the hearing entitled "Regulatory Failure: Must America Live with Unsafe Food?" We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a certain Member of the Subcommittee. In preparing your answers to these questions, please address your response to the Member who submitted the questions and include the text of the Member's question along with each of your responses.

In order to facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Monday, April 28, 2008**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Kyle Chapman, Legislative Clerk. An electronic version of your response should also be sent by e-mail to Mr. Kyle Chapman at **kyle.chapman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Kyle Chapman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

The Honorable Jan Schakowsky, Member
Subcommittee on Oversight and Investigations

The Honorable Jan Schakowsky

1. Please provide the Committee with a copy of the materials you use for your training program for the humane handling and harvesting of livestock.

2. Please describe your training program for the humane handling and harvesting of livestock in detail:

    a. Who conducted the program?

    b. What was the length of the program?

    c. What was the content of the program presentations made to employees?

    d. How many training programs were employees required to attend each year?

3. Please provide the Committee with a signed affidavit from the employees who were responsible for administering the training program verifying that the training was completed in full, per your description in response to question number two, to all employees who signed the certification letters, examples of which were provided to the Committee.

1. Please provide the Committee with a copy of the materials you use for your training program for the humane handling of livestock?

   See Exhibit A

2. Please describe your training program for the humane handling of livestock in detail:

   See Exhibit A

   a. Who conducted the program? Pablo Salas, Gustavo Manzo, Martin Laguna and Daniel Ugarte*
   b. What was the length of the program?
      Approximately 45 minutes
   c. How many training programs were employees required to attend each year?
      The entire program in exhibit A was administered once a year, but random sections of Exhibit A were reviewed with all animal handlers throughout the year on a monthly basis. The training was always conducted by one of the supervisors mentioned in section a.

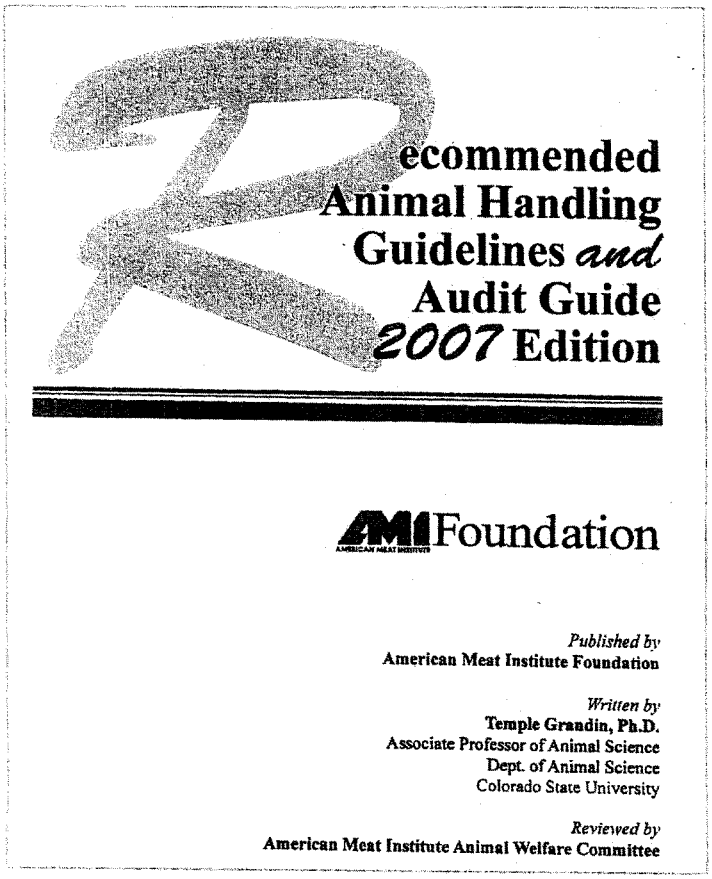
EXHIBIT

A

HALLMARK MEAT COMPANY

HUMANE HANDLING OF LIVESTOCK

REVISED: MAY 2007



INTRODUCTION

Hallmark Meat Company's (HMC) revised 2007 edition regarding Humane Handling of Livestock has enhanced embellishments to augment our collective efforts of handling cattle in a humane manner based on the AMI's 2007 Edition of Humane Handling. Listed below are sub-categories that have been supplemented into our program;

1. ***Humane Handling Mission Statement of Hallmark Meat Company***
2. ***Emergency Livestock Management Plan***
3. ***Revised Audit & Criteria Forms***
4. ***Power Point Training***

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HUMANE HANDLING OF LIVESTOCK GUIDELINES

Humane Handling Mission Statement of Hallmark Meat Company

The Humane Methods of Slaughter Act of 1978 (HMSA) states that the handling and harvesting of all livestock harvested in federally inspected meat plants are to be carried out by humane efforts. All cattle received at HMC are humanely handled in accordance to all pertinent FSIS Regulations, Directives and Notices. HMC has recently integrated the AMI's Revised 2007 Edition of Recommended Animal Handling Guidelines into our present program.

Not only do we consider it our moral duty to treat animals humanly, there are additional benefits of ensuring an animal's well-being, which includes worker safety, efficiency, profitability, and continuing to improving our high quality standards.

GENERAL OVERVIEW OF POLICIES AND PROCEDURES

Employees of HMC whose assigned duties are to handle livestock are specifically trained with regards to Humane Handling. The following are company requirements regarding the humane handling of livestock;

- Livestock must be unloaded and driven in a manner that causes minimal excitement (Battery prods or other tools used to drive animals from the trucks must be used only when necessary) and discomfort to the animal and avoids unnecessary crowding in holding pens.
- Battery prods or other tools used to drive animals will be used only when necessary to minimize or avoid excitement and injury.
- USDA regulations require that electrical prods have a voltage of 50 volts or less. Prods which have sufficient power to knock an animal down or paralyze will not be used.
- Battery prods must never be applied to sensitive parts of the animal's anatomy such as; eyes, ears, mouth, nose or anus. In practical terms, the prod should not be used on the animal's head.
- **HMC does not use any wired-in prods only battery operated prods.**
- Battery-operated prods are best for livestock handling because they provide a localized directional stimulus between the two (2) prongs.

GENERAL OVERVIEW OF POLICIES AND PROCEDURES (continued)

- Only plant-approved equipment is to be used to handle livestock - pipes, sticks, sharp pointed objects, or any item may cause harm will not be used.
- Conscious non-ambulatory livestock will be humanly stunned and removed after securing USDA IIC permission and removed in accordance with plant policy.
- Unconscious livestock will be humanly stunned and removed in accordance with plant policy.
- Stunning will be done in a manner to immediately render the animals unconscious throughout the shackling, sticking, skinning and bleeding production steps.
- Audits by Quality Control personnel will be routinely conducted to help ensure employee compliance to Company policies.
- Employees who do not follow the above policies will be subject to disciplinary action up to and including immediate termination (or removal from our Establishment for individual truck drivers found to be in noncompliance with our policies) of employment at HMC.

Listed below are additional procedures regards to the humane handling of livestock at our Establishment #336.

SECTION 313.1: LIVESTOCK PENS, DRIVEWAYS AND RAMPS

(a) Livestock pens, driveways and ramps will be maintained in good repair. They are to be free from sharp or protruding objects which may, in the opinion of the USDA Inspector, cause injury or pain to the animals. Loose boards or broken planking and unnecessary openings where the head, feet, or legs of an animal may be injured will be repaired in a timely manner.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.

(c) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

SECTION 313.2: HUMANE HANDLING OF LIVESTOCK

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Prods other implements employed to drive animals shall be used as little as possible in order to minimize excitements and injury. Any use of such implements which, in the opinion of the USDA Inspector, is excessive, is prohibited.

(c) Pipes, sharp or pointed objects, and other items which, in the opinion of the USDA inspector and/or plant management, that would cause injury or unnecessary pain to the animals will not be used to drive livestock.

(d) Disabled livestock and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in Section 313.1.

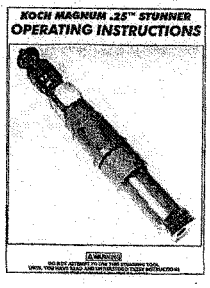
(e) The dragging of disabled animals and other animals unable to move, while conscious, is strictly forbidden.

(f) Animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for animals held overnight to lie down.

(g) Stunning methods approved in Section 313.3 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast or cut.

(h) In the event a cow becomes loose in the yard, standard procedures will be to inform the guard and calm the animal down. However if the cow becomes uncontrollable, the USDA IIC will be informed and the cow will be handled and stunned in a humane manner.

SECTION 313.3: STUNNING METHODS – MECHANICAL; CAPTIVE BOLT

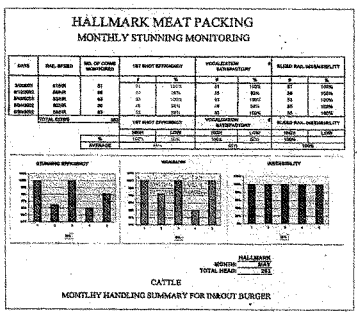


Regulatory requirements for the use of captive bolt stunners as a humane method of harvesting are listed below:

1) Captive bolt stunners are used at our facility. The Koch Magnum .25 Stunner is depicted on the right.

2) The captive bolt stunners shall be applied to livestock so as to produce immediate unconsciousness in the animals before that are shackled, hoisted, thrown, cast, or cut.

SECTION 313.15: STUNNING METHODS – MECHANICAL; CAPTIVE BOLT

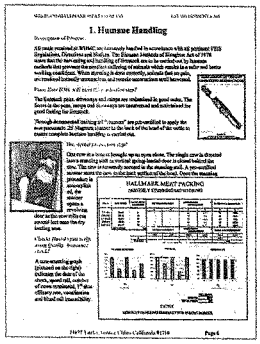

HALLMARK MEAT PACKING
MONTHLY STUNNING MONITORING

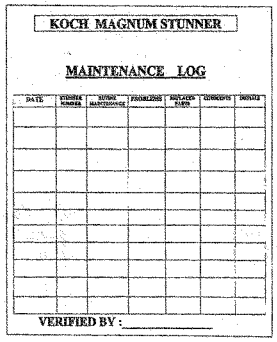
CATTLE
MONTHLY HANDLING SUMMARY FOR INHOUT BURGER

3) The stunning operation is an exacting procedure and requires a well-trained and experienced operator who must use the correct detonating charge with regard to kind, breed, size, age, and sex of the animal to produce the desired results. A monthly stunning chart covering # of cows rendered, 1st shot efficiency, vocalization and bleed rail insensibility is recorded as depicted directly to the right.

4) Stunning instruments must be maintained in good repair through a documented preventive maintenance program. Any stunning instrument found to be defective will be rejected and replaced with a properly operated stunning device.

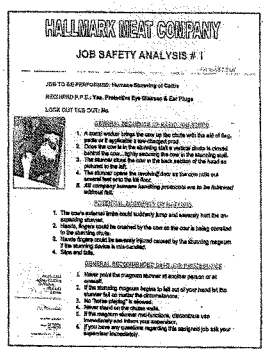
Depicted below is training forms for employee's who perform the stunning operation at our Establishment, including the daily preventive maintenance logs involving the Koch Magnum Stunner.


1. Humane Handling


KOCH MAGNUM STUNNER

MAINTENANCE LOG

VERIFIED BY : _____


HALLMARK MEAT COMPANY

JOB SAFETY ANALYSIS # 1

NON-AMBULATORY DISABLED CATTLE

WHMC follows all directives in accordance with the USDA Food Safety Inspection Service (FSIS); Directive 6900.1R1 – Humane Handling of Disabled Livestock, issued 11/2/98; Non-ambulatory disabled cattle are considered unfit for use as human food as per FSIS Notice 5-04 dated 1/12/2004.

All cattle that are non-ambulatory/disabled livestock are defined in 9 CFR 309.2 (b) as livestock that cannot rise from a recumbent position or that cannot walk, including but not limited to those broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral, etc., will be humanely condemned and will not enter the processing establishment.

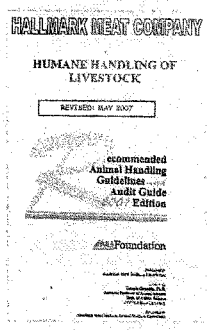
The following standard operating procedures (SOP) with regards to non-ambulatory cattle will be followed without fail;

- All "Downer" cattle located within the corrals will be segregated from other cattle and thereafter humanely stunned by a designated employee. The condemned carcass will be removed by designated employees from the corral and into a designated area where it will be picked up by a dead-stock APHIS approved hauler.

- In the event a "Downer" is delivered on a truck/trailer, a designated employee will humanely stun the cow on the truck and remove the condemned carcass to a designated area that will be removed by an independent rendering company.

- Any ante-mortem cow that becomes non-ambulatory while in the specific geographic area of the "single file chute" will be considered a "Downer." The single chute begins at the door block that opens to the bricked single file chute and ends at the steel weighted door where the actual humane stunning of cows is performed. The USDA IIC will be informed by a designated employee in the event an ante-mortem cow becomes non-ambulatory while in the designated single file chute. Once the USDA IIC has performed their applicable duties and permission is secured to humanely stun the animal, the animal will be stunned and removed from the single file chute area. The condemned carcass will be moved to a designated area and picked up by a dead-stock APHIS approved hauler.

Following the humane stunning and removal each individual downer will have its back-tag identification number recorded with the date, signature and verification being recorded for any needed future references. All information is forwarded to the USDA IIC.



Disciplinary Procedures for Cattle Handling Violations

1) Any employee of HMC found to intentionally run cattle over the top of a downer will be immediately terminated from the company.

2) No shouting or hitting of the cattle is allowed. Any employee that is observed abusing cattle in any manner will be immediately terminated from the company.

3) Any employee found to have abused an animal such as poking an object into sensitive parts of the animal such as the eyes or anus will be immediately terminated from the company.

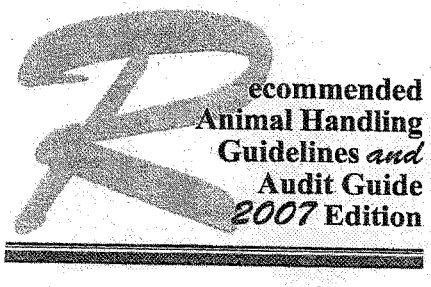
4) Any employee found to have dragged an animal while conscious will be immediately terminated from the company.

5) Any truck driver found to have utilized an electrical hot shot to unload cattle will be banned from our Establishment.

6) Any employee who fails to follow outlined and established policies will be immediately disciplined or terminated depending on an objective view of the violation at hand.

7) Any employee who has been found to have grossly mistreated an animal will be immediately terminated from the company.

Quality Control personnel and Harvest floor management will monitor all policies and procedures regarding the humane handling of cattle.



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American Meat Institute Foundation

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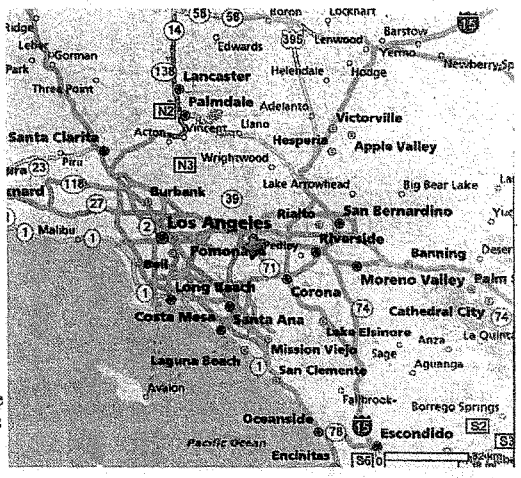
Colorado State University

Reviewed by
American Meat Institute Animal Welfare Committee

Emergency Livestock Management Plan



HMC geographic and topographic location is not germane to the many inclement climatic conditions that adversely affect other USDA inspected harvesting plants in the Continental United States, including Hawaii.

Snowfall, hurricanes, tsunamis, and tornadoes have not been a historically indigenous factor in the immediate Southern California area since or before California became a state in 1850. However, natural disasters such as earthquakes are familiar to Southern California than to other areas outside the state. Page 4 describes HMC procedures regarding roaming livestock.

Fires are not a factor in that HMC's immediate location is surrounded by non-agricultural businesses.

Flooding is not an issue in that the nearest flood control dam is located approximately 6.5 miles south south/west of HMC. This matrix of channels has been constructed to channel water to the LA River by means of new and re-enforced aqueducts.

On the next page is chronicled average air temperatures form the year 1927 to 2004 in San Bernardino County. Rainfall has not and is not a dynamic factor to the welfare of the livestock unless an anomaly such as another *El Nino* is formed again in the Pacific.

HMC follows FSIS/APHIS regulations with regards to dead-carcass removal in the event a natural disaster should terminate livestock.

To combat the hot summer weather, the corrals are maintained with populations having full access to fresh water available 24 hours/7 days a week. In addition sprinklers/sprayers have been placed on the perimeter of the corrals for auxiliary cooling purposes. Additionally, the wetting down of the corrals grounds has proven to help truncate livestock body heat.

Changing feed lot schedules and rations will be considered during a heat wave, including the control of flies and other parasites that simultaneously occur with warmer weather. HMC is cognizant that livestock can easily deal with one stress at a time but not more.

HMC's holding corrals are presently constructed so that maximum air flow is attained which helps the penned livestock.

HALLMARK MEAT COMPANY

COMPANY POLICY REQUIREMENT FOR DRIVERS OF LIVESTOCK

(Revised May 2007)

Hallmark Meat Company (HMC) has established strict requirements for the transportation of livestock to our Establishment #336. ***HMC is responsible for the behavior of any outside transporter of livestock while on company premises as per USDA Directive 6900.1.***

The following Standard Operating Procedures listed below are to be followed by all transportation drivers to our USDA Inspected Establishment. By signing below each delivery driver of livestock understands fully HMC's policies and procedures with regards to Humane Handling of all livestock;

- All applicable paperwork that is required by law must be in order and up to date when delivering livestock to HMC.
- Drivers must disclose to the Security Guard at the point of entry if he has either ambulatory or non-ambulatory livestock and the number he is delivering.
- No livestock is allowed to be unloaded unless a back tag is attached. If there is no back tag the driver will have to remain in a designated area until approval and verification is obtained prior to unloading the livestock.
- No hot shot, electric prong, or any other method that will injure and/or harm the livestock is allowed to be used.
- No excessive shouting or any other types of animal abuse is not allowed.
- If the animal is a downer the driver is to contact plant management immediately.
- If the USDA Inspector-In-Charge condemns a suspect downer after ante-mortem inspection has been completed and the driver/farmer disagrees with the cattle disposition, the animal cannot be removed from the plant premises.
- Any questions you may have are to be forwarded to plant management immediately.

By signing below, I understand fully that the procedures that are listed above must be followed at all times.

_____

Delivery Drivers Name, Signature and Date of Delivery

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

By signing below, I understand all policies and procedures that involve the Humane Handling and Harvesting of cattle (both ambulatory and non-ambulatory) at Hallmark Meat Company (HMC). I have been instructed and trained regarding my job assignment(s) as documented in our written program.

I also understand that if I have any questions regarding the strict requirements of this program with regards to my assigned job(s) or that of others, I have been instructed and understand fully that I am to notify my direct Supervisor immediately.

HALLMARK MEAT COMPANY

Employee's Printed Name and Signature Date

Trainer's Name and Signature Date

(Upon completion of this form please forward it to Pablo Salas)

PE.com

San Bernardino

Can history repeat here?

Inland Southern Californians know their own Katrina is possible. Will the region be ready for the epic earthquake, cataclysmic wildfire or terror attack that may one day come?

01:02 AM PDT on Sunday, September 11, 2005

The Press-Enterprise

In the aftermath of Hurricane Katrina, Inland residents and public officials want to know: Is the region ready for its own major disaster -- earthquake, flood, wildfire or terrorist attack -- that could kill or injure tens of thousands, flatten buildings, crumple freeways, silence telephones and snap waterlines?

Survivors would find limited food, medicine and water and no cash for supplies if ATM's aren't working.

California is considered among the best-prepared states by federal disaster planners, but the extent of devastation along the Gulf Coast is prompting local agencies to examine their ability to respond to a cataclysmic event.

Evacuation of many of the Inland area's 3.2 million residents might be ineffective after a major quake, particularly when it comes to rescuing the elderly and disabled.

More than a third of Inland hospitals still do not meet tougher earthquake-safety standards and might be unusable after a major quake.

Inland officials aren't sure they could provide shelter or medical care in a mass evacuation of the city of Los Angeles, whose population is about that of Louisiana.

Rescuers in Riverside and San Bernardino counties would have trouble talking to each other because they use different radio systems.

The failure of governments to evacuate thousands in the path of Hurricane Katrina, especially New Orleans residents without transportation, is something emergency officials everywhere need to take note of, said Redlands resident Richard A. Andrews, the former director of the state Office of Emergency Services, which oversees disaster preparedness.

CHAIN OF COMMAND

California's Emergency Plan makes clear who is responsible for handling disasters, such as earthquakes, fires and floods, and how additional help is requested.

Here is the chain of command, from first responders to state and federal offices:

Field - First responders, such as police and fire agencies.

Local government - Counties, cities and special districts within an Operational Area. They operate local emergency operations centers that can direct the response to an incident.

Operational Area - All political subdivisions within a county. The Operational Area provides communication and coordination between local jurisdictions and state Office of Emergency Services regions.

Region - The state is organized into three Office of Emergency Services regions, six mutual-aid

"We haven't faced that in California, and I don't think the nation has faced it on this scale," Andrews said of the evacuation of an entire city with a half-million people.

Democratic Sen. Barbara Boxer, a frequent critic of the Bush administration, said last week that she is worried that the Federal Emergency Management Agency, criticized for its slow response in the Gulf Coast, is not prepared to help if a catastrophic earthquake hits California.

"I want to see how they plan to move quickly, immediately, and have the resources that are necessary to meet the worst scenario that you can imagine," she said.

FEMA started a series of workshops last year to prepare Louisiana officials for a massive hurricane or flood in New Orleans, but it had not finished, said spokeswoman Mary Margaret Walker. Other workshops on how to handle a large-scale earthquake were to take place in California.

"We didn't get to California," she said.

The state remains on the agenda, Walker said.

Riverside County supervisors last week called for a report by Tuesday on the strengths and flaws of the county's disaster-relief plan.

"I think we have some lessons to learn from the past week, realizing the federal government is not going to come to our rescue in the first 72 hours," said Supervisor Roy Wilson, whose desert district is riddled with major earthquake faults.

Disaster planners must consider the county's poor and elderly with limited access to transportation and scant resources, supervisors said.

regions for fire and seven law-enforcement and coroner mutual-aid regions. Office of Emergency Services regional administrators manage and coordinate resources among counties within mutual-aid regions when help is requested.

State government - The Office of Emergency Services director coordinates state disaster preparedness and response, under the authority of the California Emergency Council. The council advises the governor during an emergency and on preparedness issues. The governor has authority to mobilize the California National Guard and request federal aid in a disaster.

Federal government - Once the governor requests federal help, the Federal Emergency Management Agency can mobilize people and equipment for search and rescue, electrical power, food, water, shelter and other basic needs. Long-term financial help is available to individual disaster victims and state and local governments.

Televised images of people clinging to rooftops or wading through putrid floodwaters in New Orleans have disturbed most Americans and unnerved public officials in charge of disaster preparedness.

Local communities must be ready to handle a massive evacuation from the Los Angeles Basin, said Riverside County Fire Chief Craig Anthony.

"That would be our equivalent to Louisiana."

Region at Risk

California's two most powerful faults -- the San Andreas and the San Jacinto -- slice through the Inland Empire. A major eruption of the southern stretch of the San Andreas has been expected by experts for more than 20 years.

That section of the fault, which weaves from the Cajon Pass northwest of San Bernardino to the Salton Sea in the southeast corner of the state, is capable of at least a magnitude 7.5 earthquake, said seismologist Lucy Jones, scientist-in-charge of the U.S. Geological Survey's Southern California Earthquake Hazards

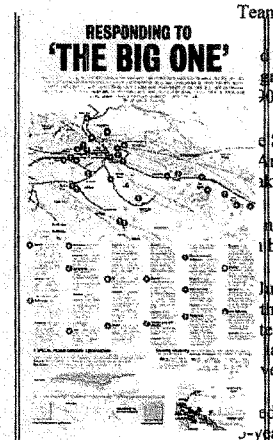


Illustration: Click to enlarge

Team in Pasadena.

some seismologists say the fault is overdue because the last major quake, a nitude 7.1, struck the southern part of the fault near Thousand Palms in 0.

San Jacinto fault, which runs from Lytle Creek in San Bernardino County nza in Riverside County and beyond, is also capable of a 7.5 magnitude ke.

ot always the earthquake itself, but fires, landslides and dam failures that be dangerous, Jones said.

ly, the state said the two-mile-long dam at Lake Perris could fail in a major quake, flooding low-lying communities and sending billions of gallons of r rushing toward homes and people in Lake Elsinore. Officials are draining ake to drop the level by 25 feet, a process that may not be completed until ember, to examine the dam.

d, Riverside County's emergency official, said the state has yet to update a -year-old map that would show where flooding would occur in one of California's fastest-growing regions should the Lake Perris dam fail. Susan Sims, a spokeswoman for the California Department of Water Resources, said it would be ready by the end of this month.

The impact of a 7.4 magnitude quake on the San Andreas fault six miles north northwest of Palm Springs would be felt 50 miles away, killing 900 people in the city of Riverside and San Bernardino County and injuring 14,699 under a scenario developed by the state Office of Emergency Services. In all, the region could suffer $13.3 billion in damage.

"I was shocked at these numbers," said Carmen Nieves, Riverside's emergency services coordinator, who requested the scenario a few years ago for a disaster drill.

Cynthia Spalding Vermeule, a 40-year-old Hemet resident, said she's ready for the worst.

She is co-manager of Hemet Hospice Thrift Store, which occupies a building in downtown Hemet that has not been retrofitted to strengthen it against quakes. A sign taped to the window states: "This is an unreinforced masonry building. You may not be safe inside or near unreinforced masonry buildings during an earthquake."

"If it starts to shake, I think about where I would run to," said Vermeule, who added that she would try to get customers out of the building to safety.

Good News

Statewide, Caltrans has spent more than $2 billion strengthening 2,300 highway and freeway bridges -- 98 percent of state-owned bridges. Improvements that began after the 1989 Loma Prieta earthquake include securing bridge decks to their supports, using steel reinforcement in new columns and encasing older concrete columns in steel.

Caltrans officials say the goal is to make bridges earthquake resistant, not earthquake proof.

Major retrofitted freeway interchanges in the Inland region include the junctions of interstates 10 and 215 in San Bernardino, I-10 and Interstate 15 in Ontario and Highway 91 and I-15 in Corona. When completed, the interchange of I-215 and highways 91 and 60 under construction in Riverside will better withstand a major quake, Caltrans spokesman Thomas Knox said.

If disaster struck the Inland region as quickly as floods drowned New Orleans, local officials would follow the state's detailed and oft-rehearsed Emergency Plan in requesting aid from neighboring cities, counties and the state.

The governor could mobilize the California National Guard, which can respond to any part of the state within 24 hours of receiving orders, said Maj. Jon Siepmann.

Siepmann said 12,000 of the state's 20,000-Guard force are in the state right now. About 5,000 are in Iraq, Afghanistan, Qatar, Kosovo and Guantanamo Bay, Cuba, supporting various overseas missions. Some 1,000 have been called to duty for Katrina rescue and recovery efforts.

DeeAnn Bradley / The Press-Enterprise

Cynthia Spalding Vermeule co-manages th Hemet Hospice Thrift Store, which is in an unreinforced masonry building. A sign outside warns of the quake risk of such structures.

Once the governor requests federal help, the president could order Marines from Camp Pendleton in San Diego County deployed to the Inland area to assist, said base spokesman Lance Cpl. Patrick Carroll.

Evacuation Plans

If there is a weakness in disaster preparedness statewide, it is planning to evacuate hundreds of thousands of people as in Louisiana, said Andrews, who headed the Office of Emergency Services from 1991 to 1998. He's now an adviser to the federal Homeland Security Department.

Many local governments may be unprepared, he said.

The geography of the Inland area -- sandwiched between mountains, deserts and dense population centers -- could be especially problematic. Damaged freeway bridges could cut off escape routes on interstate and state highways.

Mountain residents would find it tough to evacuate on roads that already are prone to closures from falling rock and mudslides.

During the 2003 firestorms, planning was key in evacuating more than 60,000 people down narrow roads in the San Bernardino Mountains without panic, said Denise Benson, San Bernardino County's office of emergency services manager.

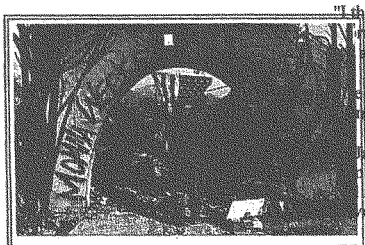
"They knew what the expectations were and what the action would be on the part of local government," she said.

Coral Albee-Grimwood and her husband, Pat Grimwood, evacuated the mountain community of Cedar Glen. Coral said residents were orderly in their departure, even though there was no one to direct traffic.

Martha Foley, a Big Bear City resident, said she witnessed a smooth relocation during the 2003 wildfires. Mountain communities were evacuated in groups over a number of days, with her community told to leave on

the third day.

Foley, 55, stayed at her mother's house and witnessed a well-organized scene at the former Norton Air Force Base, where thousands made a temporary home. As a postal worker, she went to work at the base, where the Postal Service had set up a temporary mail site for displaced mountain residents.



2003 / The Press-Enterprise
Larry Smith straightens the flag he hung in the doorway of his friend's San Bernardino home after it was destroyed in the 2003 Old Fire. Smith had been living there and lost everything.

"I thought it went incredibly smooth," she said. "It was a lot of work, but everybody just comes together in those times. It's amazing how it happens. Everybody is so close."

The evacuation of Corona residents downstream from Prado Dam did not go as smoothly.

In January, engineers found a small leak in the dam as historic rainfall drenched the region. The U.S. Army Corps of Engineers did not know the affected area was in Corona, so it notified Riverside County officials instead.

When Corona officials finally spoke with the agency, it was unclear how great the risk was, said Lynn Mata, Corona's emergency manager. So the city ordered the evacuation of 2,000 residents below the dam. School and city buses were available to help evacuate but weren't needed, she said.

Residents criticized city officials for waiting more than seven hours after they were notified of the problem to evacuate neighborhoods downstream, a process that took three hours.

Massive evacuations would pose tremendous challenges for nursing homes, in particular, directors say. Most homes rely on private bus companies and ambulances to move their residents, but they might find few available if homes are counting on the same firms. If roads are impassible, reaching the homes would pose additional problems.

"That would probably be a problem we'd have to address using private vehicles," said Janet Dial, director of staff development for California Nursing & Rehabilitation Center in Palm Springs. "I think it would be improvised at the time."

Her 80-bed facility doesn't have vehicles of its own, but Dial said after watching the Hurricane Katrina disaster, she might question her corporate directors about the need for them.

Evacuee Care

Public-health officials are re-examining a long-held belief that some of Riverside County's 15 hospitals would be useable and accessible after a major quake.

"We have to think what will happen if none are there," said Michael Osur, deputy director of public health. "What if hospitals in neighboring counties are not there?"

California hospitals fall under a 2008 deadline to upgrade or replace buildings at risk of collapse in a strong earthquake. Twelve of the Inland region's 33 acute-care hospitals have requested extensions of as long as five years.

A 2001 state survey found that 29 of 80 buildings at Riverside County's 15 acute-care hospitals are at risk of

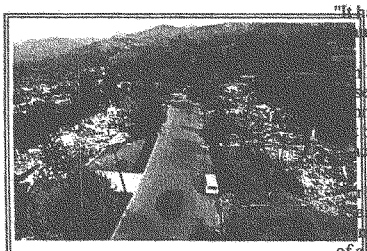
collapse during a major quake. In San Bernardino County, 53 of 129 structures at 18 hospitals are at risk.

Many Inland hospitals already have plans to retrofit or replace buildings that don't meet current earthquake safety standards. Nearly $2 billion worth of projects are planned by Riverside and San Bernardino county hospitals over the coming decade.

Without permanent useable buildings, hospital tents the county has purchased with federal anti-terrorism funds may help. Caches of medicine and medical supplies may be too small.

"We've got to think much bigger," Osur said.

March Air Reserve Base spokesman Maj. Don Traud said the base could provide shelter for several hundreds evacuees in Riverside County within 24 hours and could become a staging area for troops supporting disaster-relief efforts here. The base's 13,300-foot runway, the longest in Southern California, was built to handle loaded B-52 bombers and giant C-5 cargo planes.



2003 / The Press-Enterprise

Eight families on a single block in San Bernardino's Del Rosa neighborhood lost their homes in the 2003 Old Fire. Flames forced residents of several communities to flee their homes.

"It has a better chance to survive than most other runways," said.

Bernardino International Airport, the former Norton Air e, was used to house evacuees from the 2003 firestorm. But y Chua, the airport's marketing director, said the base might be available again because some hangars used to house uees have since been leased to tenants.

s Baker, director of preparedness and response for the nd Valley Chapter of the American Red Cross, said she has tified 300 locations that could serve as shelters in the event of a major disaster, including some public schools. The chapter keeps seven trailers stationed around San Bernardino County, each stocked with 250 to 1,000 sleeping cots and blankets.

The Riverside County Chapter of the Red Cross has 16 trailers stationed in strategic locations with a total of about 3,000 cots and blankets, said spokeswoman Sandy Lowry. The chapter keeps limited supply of water and snacks at its offices.

Riverside County also has arrangements with private vendors to supply food, water and supplies, said Tony Coletta, emergency services coordinator.

Retrieving Bodies

If the Inland region suffered a massive death count like that feared in New Orleans, both Riverside and San Bernardino counties would need help from neighboring counties -- including Los Angeles and Orange -- and the federal Disaster Mortuary Operational Response Team. The federal team would fly in mobile morgues that could be set up at various sites, such as airport hangars, ice-skating rinks and cemeteries.

San Bernardino County's morgue can hold 100 bodies. The county has identified 12 to 15 sites for possible temporary holding facilities, said Rocky Shaw, lead supervising deputy coroner.

Riverside County can store as many as 275 bodies in its Perris and Indio facilities and has a 75-foot refrigeration truck where 100 more bodies could be stored, said Curtis James, supervising deputy coroner. Also, 10 fire stations scattered throughout the county have kits that include body bags, cameras, latex gloves

and other equipment needed to process bodies.

In an extreme case, San Bernardino County's mass-casualty plan calls for a mass burial.

Utilities

Problems exist in the ability of Inland first responders to talk to each other.

Riverside County has pumped slightly more than $1 million in homeland-security funding over the past 18 months into making sure that county radios can communicate with city radios. Some departments were using 400-megahertz systems, while others were using 800 megahertz.

But, the county could have problems talking to other agencies in the state. San Bernardino County uses a different system.

The California Law Enforcement Mutual Aid Radio Systems, operated by the state Office of Emergency Services during disasters, is antiquated and requires a line of sight to operate.

"Once it becomes overwhelmed, it becomes ineffective," said Lt. Joe DeArmond, disaster-response coordinator for Riverside County Sheriff's Department.

If cell phone towers topple during a quake and radio system is busy, law-enforcement and emergency-services personnel would not be able to talk to each other or coordinate rescues and other efforts, he said.

In San Bernardino County, many police agencies and the Sheriff's Department pooled homeland-security money to buy Red Channel, an interagency radio system. The $4 million system should be installed next summer and would enable police agencies to better coordinate a regional response to a disaster.

A major quake could knock out telephone, electrical power, natural gas, sewer and water service for some time.

The Southland's two major phone companies, SBC and Verizon, could lose a large number of poles, killing telephone service to a large area. Disaster crews would respond as soon as it is safe to begin repairs, Verizon spokesman Jon Davies said.

Southern California Edison's service area is so large that if it loses a transmission line, transformer or substation, it can avoid a massive power loss by routing power from another part of the region, said Ron Ferree, director of grid operations. The utility stores spare parts to repair power stations throughout the region.

About 47,000 miles of natural-gas pipelines crisscross California, and the main transmission lines are monitored constantly, said Denise King, spokeswoman for the Southern California Gas Co. The lines can be shut down remotely and gas rerouted, King said. However, the U.S. Geological Survey believes a major earthquake could move a pipeline by as much as 20 feet, a fact that King said the gas company's engineers recognize.

There are no sensors in residential areas so residents have to rely on their sense of smell to alert them to a rupture, King said by phone.

Kinder Morgan Energy Partners LP, which operates the petroleum pipeline through the Cajon Pass to Las Vegas, has safeguards that include sensors to automatically shut down the line if it ruptures. The pipeline is designed to move with the earth, said Rick Rainey, spokesman for the Houston-based company. The steel lines could be replaced within hours.

Wake-up Call?

Inland officials all said they believe this area is well-prepared to cope with a disaster, but after seeing the devastation wrought by Katrina, they are wondering what could go wrong here.

"This is a call to arms," said Mary Moreland, director of the Riverside County Office of Emergency Services.

The biggest challenge the county faces is its geographic expanse of 7,200 miles with remote mountain and desert communities that may be hard to reach, she said.

Related

Digital Extra: Hurricane Katrina

Digital Extra: Epicenter

Digital Extra: Fireseason 2005

State Sen. Nell Soto, D-Pomona, asked Gov. Schwarzenegger last week to reinstitute the Blue Ribbon Commission that was formed after the deadly wildfires of 2003. She wants the commission to study disaster preparedness beyond just wildfires.

There was no immediate response from Schwarzenegger.

"It is only a matter of time before California suffers another major wildfire, flood, earthquake or other major calamity," Soto said.

AMI Foundation

CATTLE AND CALVES SLAUGHTER AUDIT FORM

Date:_____ Time:_____

Plant:_____ Auditor:_____

Weather:_____ Line Speed:_____

Stunner Type:_____ Operator:_____

Plant Contact Name:_____ Phone:_____

Email:_____ Establishment No.:_____

CORE CRITERIA 1: EFFECTIVE STUNNING — Conventional Only

Score 100 cattle in plants with line speeds greater than 100 cattle per hour. Fifty cattle should be audited in slower plants processing fewer than 100 head per hour. Ninety-five percent accuracy is required for a passing score. If audit is conducted in a religious slaughter facility, skip to Core Criteria 2.

It can be helpful to note observations about missed stuns using the following guide:

X = stunned correctly
G = stunning failed due to apparent lack of maintenance
A = missed stun due to poor aim

Animal Number:

1	11	21	31	41	51	61	71	81	91
2	12	22	32	42	52	62	72	82	92
3	13	23	33	43	53	63	73	83	93
4	14	24	34	44	54	64	74	84	94
5	15	25	35	45	55	65	75	85	95
6	16	26	36	46	56	66	76	86	96
7	17	27	37	47	57	67	77	87	97
8	18	28	38	48	58	68	78	88	98
9	19	29	39	49	59	69	79	89	99
10	20	30	40	50	60	70	80	90	100

Stun Efficacy Percent _____

Notes:

_____

_____

_____

1

CORE CRITERIA 2: BLEED RAIL INSENSIBILITY — Conventional and Religious

Any sensible animal on the bleed rail constitutes an automatic audit failure. It is CRITICAL that animals showing signs of a return to sensibility be restunned immediately. There is "zero tolerance" for beginning any procedures like skinning the head or leg removal on any animal that shows signs of a return to sensibility. However, it is important to complete the audit and note observations about insensibility using the following guide:

X = completely insensible; no signs of return to sensibility
E = eyes moved when touched
BL = blinking
RB = rhythmic breathing
VO = vocalization
RR = righting reflex/animal attempts to lift head

Note signs of sensibility observed by animal number:

1	11	21	31	41	51	61	71	81	91	
2	12	22	32	42	52	62	72	82	92	
3	13	23	33	43	53	63	73	83	93	
4	14	24	34	44	54	64	74	84	94	
5	15	25	35	45	55	65	75	85	95	
6	16	26	36	46	56	66	76	86	96	
7	17	27	37	47	57	67	77	87	97	
8	18	28	38	48	58	68	78	88	98	
9	19	29	39	49	59	69	79	89	99	
10	20	30	40	50	60	70	80	90	100	

Percent Insensible _____

Notes:

_____

_____

_____

CORE CRITERIA 3: SLIPS AND FALLS — Conventional and Religious

3A: Count the number of cattle that slip or fall during unloading. In large plants where multiple vehicles are continuously unloaded, 100 cattle from three different vehicles are scored. For all species, an equal number of animals from each deck should be scored. Vehicles should be scored in the order of arrival at the unloading ramp. In small plants where vehicles are not continuously unloaded, a single vehicle should be scored. If no vehicle arrives, the scoresheet is marked "unloading not observed."

X = no slipping or falling F = fell S = slipped

1____	11____	21____	31____	41____	51____	61____	71____	81____	91____
2____	12____	22____	32____	42____	52____	62____	72____	82____	92____
3____	13____	23____	33____	43____	53____	63____	73____	83____	93____
4____	14____	24____	34____	44____	54____	64____	74____	84____	94____
5____	15____	25____	35____	45____	55____	65____	75____	85____	95____
6____	16____	26____	36____	46____	56____	66____	76____	86____	96____
7____	17____	27____	37____	47____	57____	67____	77____	87____	97____
8____	18____	28____	38____	48____	58____	68____	78____	88____	98____
9____	19____	29____	39____	49____	59____	69____	79____	89____	99____
10____	20____	30____	40____	50____	60____	70____	80____	90____	100____

Percent falling _____ Percent slipping _____

Note where slipping/falling occurred:

Notes:

_____

_____

_____

3B: Count the number of cattle that 1) slip and 2) fall during handling in any of the following locations: crowd pen, single file chute, barns, alleys or stunning box. A slip is recorded when a knee or hock touches the floor. In cattle stun boxes and the single file chute, a slip should be recorded if the animal becomes agitated due tomultiple short slips. A fall is recorded if the body touches the floor. One percentor fewer falls and three percent or fewer slips are required for a passing score.

X = no slipping or falling F = fell S = slipped

1	11	21	31	41	51	61	71	81	91
2	12	22	32	42	52	62	72	82	92
3	13	23	33	43	53	63	73	83	93
4	14	24	34	44	54	64	74	84	94
5	15	25	35	45	55	65	75	85	95
6	16	26	36	46	56	66	76	86	96
7	17	27	37	47	57	67	77	87	97
8	18	28	38	48	58	68	78	88	98
9	19	29	39	49	59	69	79	89	99
10	20	30	40	50	60	70	80	90	100

Percent falling _____ Percent slipping _____

Note where slipping/falling occurred:

Notes:

_____

_____

_____

CORE CRITERIA 4: VOCALIZATION — Conventional and Religious

Monitor the number of cattle that vocalize (provoked by stress or agitation) in the crowd pen, lead-up chute stunning box or restrainer. Vocalizing animals in the crowd-pen and lead up chute are scored during active handling. Score an animal as a vocalizer if it makes any audible vocalization. Three percent or less of cattle should moo or bellow. In Kosher or Halal operations or any operation using a head holder, up to five percent vocalization is acceptable for a passing score. It is helpful to note the possible cause of vocalization using the codes below:

X = non-vocalizer	P = prod
S = stun	F = fell or slipped
U = unknown cause	R = restrainer
M = missied stuns	SE = sharp edges
UN = unprevoked	

1	11	21	31	41	51	61	71	81	91	
2	12	22	32	42	52	62	72	82	92	
3	13	23	33	43	53	63	73	83	93	
4	14	24	34	44	54	64	74	84	94	
5	15	25	35	45	55	65	75	85	95	
6	16	26	36	46	56	66	76	86	96	
7	17	27	37	47	57	67	77	87	97	
8	18	28	38	48	58	68	78	88	98	
9	19	29	39	49	59	69	79	89	99	
10	20	30	40	50	60	70	80	90	100	

Percent vocalizing: _____ Percent vocalizing: _____

Notes:

_____

_____

_____

CORE CRITERIA 5: PROD USE — Conventional and Religious

Monitor the percentage of 100 cattle prodded with an electric prod at the restrainer entrance.Twenty-five percent or fewer cattle should be prodded for passing score. If multiple employees use prods, score 100 animals passing by each employee. Add the percentages together to determine final score. Note whether or not a prod was used for each animal and the apparent reason for prod use:

X = moved quietly without an electric prod
P = electric prod used without apparent reason
B = electric prodded in response to balking

1____	11____	21____	31____	41____	51____	61____	71____	81____	91____
2____	12____	22____	32____	42____	52____	62____	72____	82____	92____
3____	13____	23____	33____	43____	53____	63____	73____	83____	93____
4____	14____	24____	34____	44____	54____	64____	74____	84____	94____
5____	15____	25____	35____	45____	55____	65____	75____	85____	95____
6____	16____	26____	36____	46____	56____	66____	76____	86____	96____
7____	17____	27____	37____	47____	57____	67____	77____	87____	97____
8____	18____	28____	38____	48____	58____	68____	78____	88____	98____
9____	19____	29____	39____	49____	59____	69____	79____	89____	99____
10____	20____	30____	40____	50____	60____	70____	80____	90____	100____

Percent prodded____

Percent balking____

Notes:

_____

_____

_____

CORE CRITERIA 6: WILLFUL ACTS OF ABUSE — Conventional and Religious

Any willful act of abuse is grounds for automatic audit failure. Willful acts of abuse include but are not limited to: 1) dragging a conscious,non-ambulatory animal; 2) intentionally applying prods to sensitive parts of the animal like the eyes, ears, nose or rectum; 3) deliberate slamming of gates on livestock; 4) purposeful driving of livestock on top of one another; 5) hitting/beating an animal. Note any such acts observed.

Were any willful acts of abuse observed?

Yes ____ No ____

If yes, detail incident(s) below:

_____

_____

_____

Notes:

_____

_____

_____

CORE CRITERIA 7: ACCESS TO WATER — Conventional and Religious

Observe access to water. Do animals in all pens have access to clean drinking water?

Yes ____ No ____

Notes:

_____

_____

_____

Final Scoring – Cattle and Calves Audit

Core Criteria	Passing Score	Actual Score
Core Criteria 1: Effective Stunning	95% or greater accuracy	_____
Core Criteria 2: Bleed Rail Insensibility	100% insensible	_____
Core Criteria 3: Slips and Falls		
3A: Truck Unload	1% or less falls	_____
	3% or less slips	_____
3B: In Plant	1% or less falls	_____
	3% or less slips	_____
Core Criteria 4: Vocalization	3% or less	_____
	5% or less with head-holder/ritual	_____
Core Criteria 5: Prod Use	25% or less prodded	_____
Core Criteria 6: Willful Acts of Abuse	No willful acts of abuse	_____
Core Criteria 7: Access to Water	Yes – water provided	_____

Plant passed all numerically scored criteria? Yes ____ No ____

_____ _____

Auditor signature Date

SECONDARY AUDIT ITEMS

These items may be helpful in gathering general information about a facility. However, because they involve a high degree of subjectivity and because they are almost impossible to score objectively, they should not be used in determining whether a facility passes or fails an audit.

1. Does the facility have a documented training program for its employees or use an outside training program to teach the principles of good animal handling?

   Yes ____ No ____

2. Does the facility have a protocol that is written or widely understood for handling non-ambulatory animals?

   Yes ____ No ____

3. Are facility personnel trained in handling non-ambulatory animals?

   Yes ____ No ____

4. Do they inspect the facility weekley and document for repair any damage or sharp protrusions that may injure animals?

   Yes ____ No ____

5. Does the facility provide special training to stunner operators to ensure proper equipment use and stunning efficacy?

   Yes ____ No ____

6. Does the facility have a protocol for stunning equipment maintenance?

   Yes ____ No ____

7. Does the facility train its personnel and have a written procedure or protocol about how to handle a sensible animal on the bleed rail?

   Yes ____ No ____

8. Is non-slip flooring provided throughout the facility?

   Yes ____ No ____

9. Are non-electrical devices the primary tool used to move livestock?

   Yes ____ No ____

10. Do crowd pens generally appear to be less than 75 percent full?

    Yes ____ No ____

11. Are animals unloaded from trucks promptly (target is within one hour of delivery)?

    Yes ____ No ____

12. If mounting behaviors were observed, are animals that chronically mount removed from the pen?

    Yes ____ No ____ NA ____

13. Does the company perform internal audits at least weekly?

    Yes ____ No ____

14. Does the company have an emergency management plan for livestock on file?

    Yes ____ No ____

Notes related to secondary audit items:

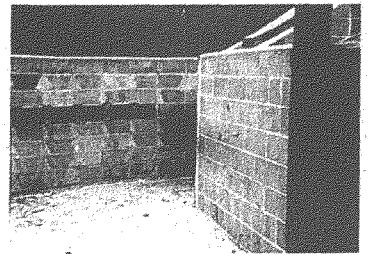
_____

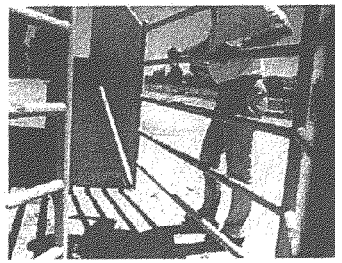
_____

_____

Trouble Shooting Handling

1. Distractions that cause balking
2. Slick floor causes agitation
3. Facility design problem
4. Employee training issue



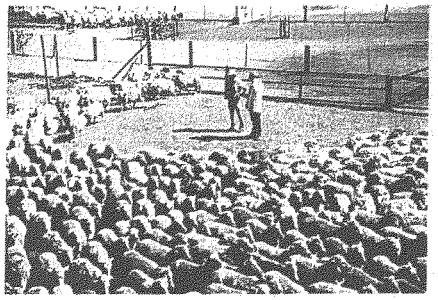


Handling Cattle

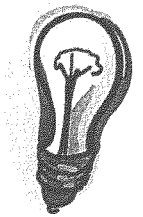
2nd Edition

Temple Grandin
Department of Animal Sciences
Colorado State University

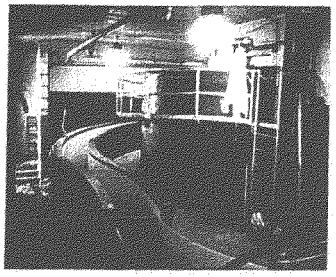
Colorado State University
Knowledge to Go Places



Training Employees

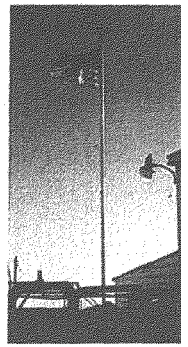


1. Flight Zone Principles
2. Point of Balance
3. No Yelling
4. Move Cattle in Small Groups
5. Fill Crowd Pen Half Full
6. Get Electric Prods Out of People's Hands



Most Common Distractions

- Reflections on water or metal
- Air blowing towards approaching cattle
- Moving people or equipment
- Chute entrance too dark
- Visual cliff in conveyor restrainer
- Shadows high contrasts

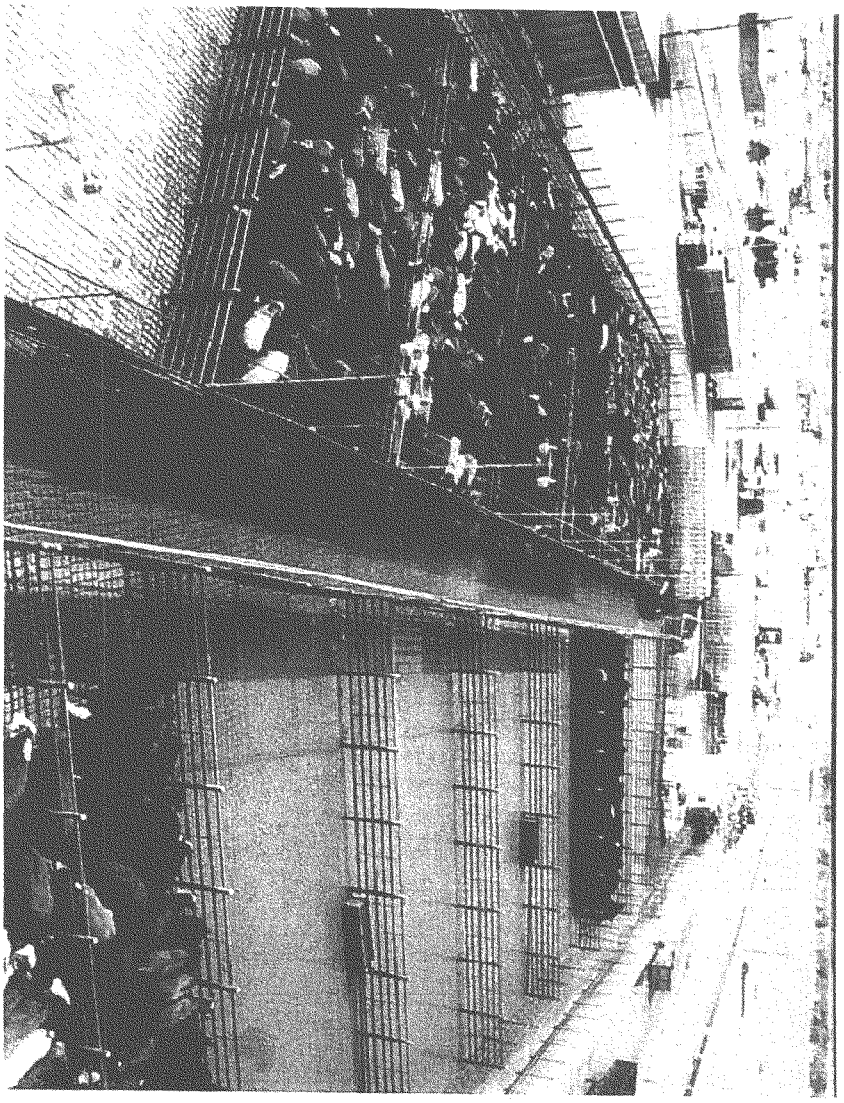


STEER VISION DIAGRAM
Cattle have panoramic
shown in this drawing.
covered by the dome
circle, represents the
field of vision in which
depth perception. The
shaded area in front of the
animal's head represents
binocular field. It is
caption in this 25 to 50
area.

Flight Zone Diagram

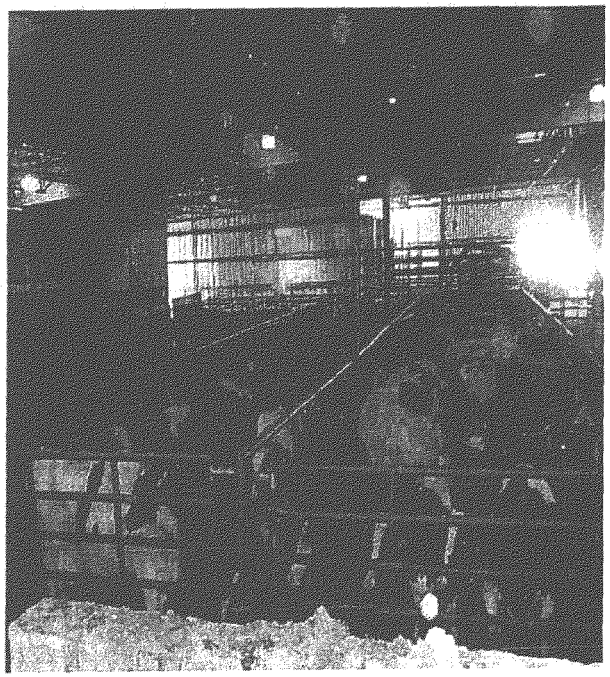
Euthanasia of Non-Ambulatory Cattle

- Must have protocol for euthanasia
  - Only trained and designated personnel can euthanize
  - .25 caliber captive bolt shot to the "X" between the eyes and ears
  - No eye blink reflex or signs of sensibility before movement
- Keep track of N-A cattle.
  - There may be a common supplier or location

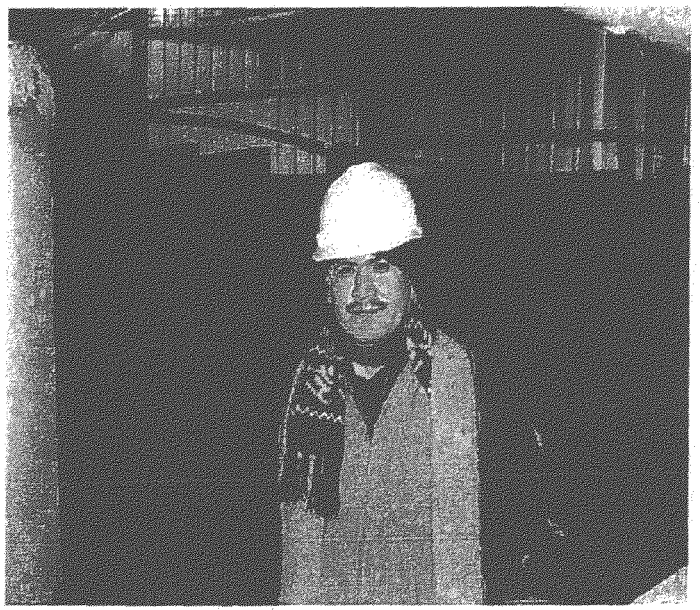


Holding and Staging Area Issues

- Cows and bulls don't mix!
- Keep distractions out of sight if possible (this includes people)
- Use time on truck to determine holding time in barn if possible
- Use cattle condition to determine placement in harvest line up



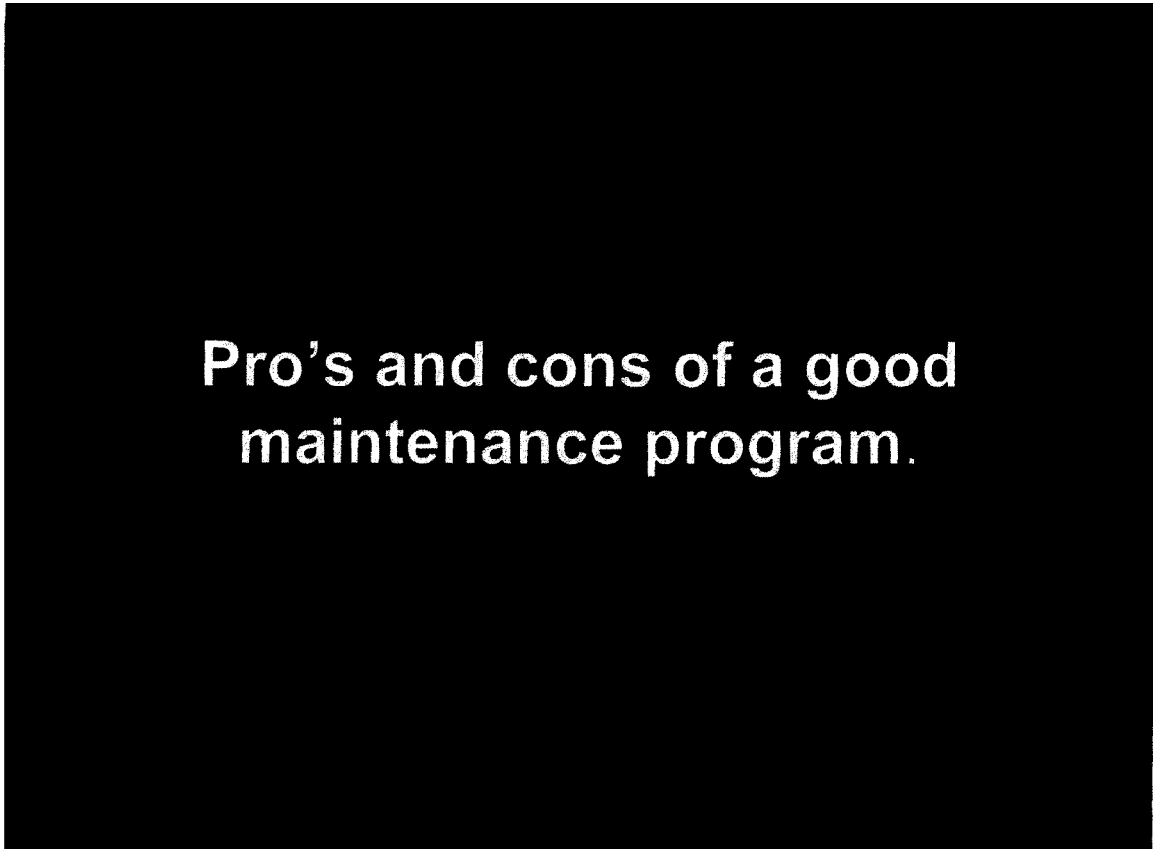
Attributes of a good cow handler:



- Calm
- Quiet
- Logical
- Observational
- Experienced
- Patient

Pro's

- Longer life of your equipment.
- Improved safety and employee engagement.
- Increase MTBF & Increased efficiencies.
- Better life cycle costs/ROI.
- Improved "Well-Being" of our animals.


Pro's and cons of a good
maintenance program.


How do we initiate a program that
can rectify issues that affect
animal well being?
Collaboration

Con's

- It costs money !!
- It takes commitment !!
- It takes collaboration !!

Collaboration will.....

Reduce the risk of injury to our animals.

Reduce the risk of stress to our animals.

Allow us to monitor and adjust Our animal well being standards.

Collaboration will also……

Increase efficiencies.

Improve working relationships

Reduce the cost of R & M.


Collaborate with maintenance, they know the mechanical/engineering methods.
Give the maintenance team Animal Welfare Training.
Train handlers and operators to do minor maintenance repairs.

Develop a culture that ensures our property and equipment is maintained to a standard....

.....A Standard That Will Not Compromise Animal Well-Being.

Reactive

Long term high cost.

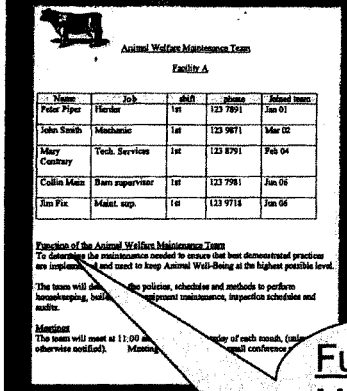
Property and equipment in poor shape.

Morale suffers. Safety is poor.

Will compromise Animal Well-Being

Maintenance culture

The type of maintenance culture a business develops is related to the standard of animal welfare within that business.



Animal Welfare Maintenance Team

Facility A

Name	Job	shift	phone	Joined team
Peter Piper	Herder	1st	123 7891	Jan 01
John Smith	Mechanic	1st	123 9871	Mar 02
Mary Contrary	Tech. Services	1st	123 8791	Feb 04
Collin Main	Barn supervisor	1st	123 7981	Jun 06
Jim Fix	Maint. sup.	1st	123 9718	Jun 06

Function of the Animal Welfare Maintenance Team

To determine the maintenance needed to ensure that best demonstrated practices are implemented and used to keep Animal Well-Being at the highest possible level.

The team will determine the policies, schedules and methods to perform housekeeping, building and equipment maintenance, inspection schedules and audits.

Meetings

The team will meet at 11:00 am on the first Monday of each month, (unless otherwise notified). Meetings will be held in the small conference room.

Function of the Animal Welfare Maintenance Team

Determine the maintenance and policies needed to ensure that best demonstrated practices are implemented and used to keep Animal Well-Being at the highest possible level.

Proactive

Long term will reduce costs.
Property and equipment in better shape.
Systems in place to prevent issues.

This will enhance Animal Well-Being.

Penetrating Captive Bolt with No Air Injection

causes much lower levels of central nervous system tissue contamination

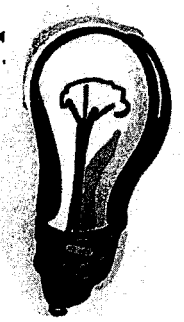
2/108 cattle- faint positive on immuno-assay

Horlocher et al., 2002

2/726 cattle positive on immuno-assay

Lucker et al., 2002

THERE IS A ZERO TOLERANCE FOR HOISTING AN ANIMAL THAT IS SHOWING OBVIOUS SIGNS OF SENSIBILITY



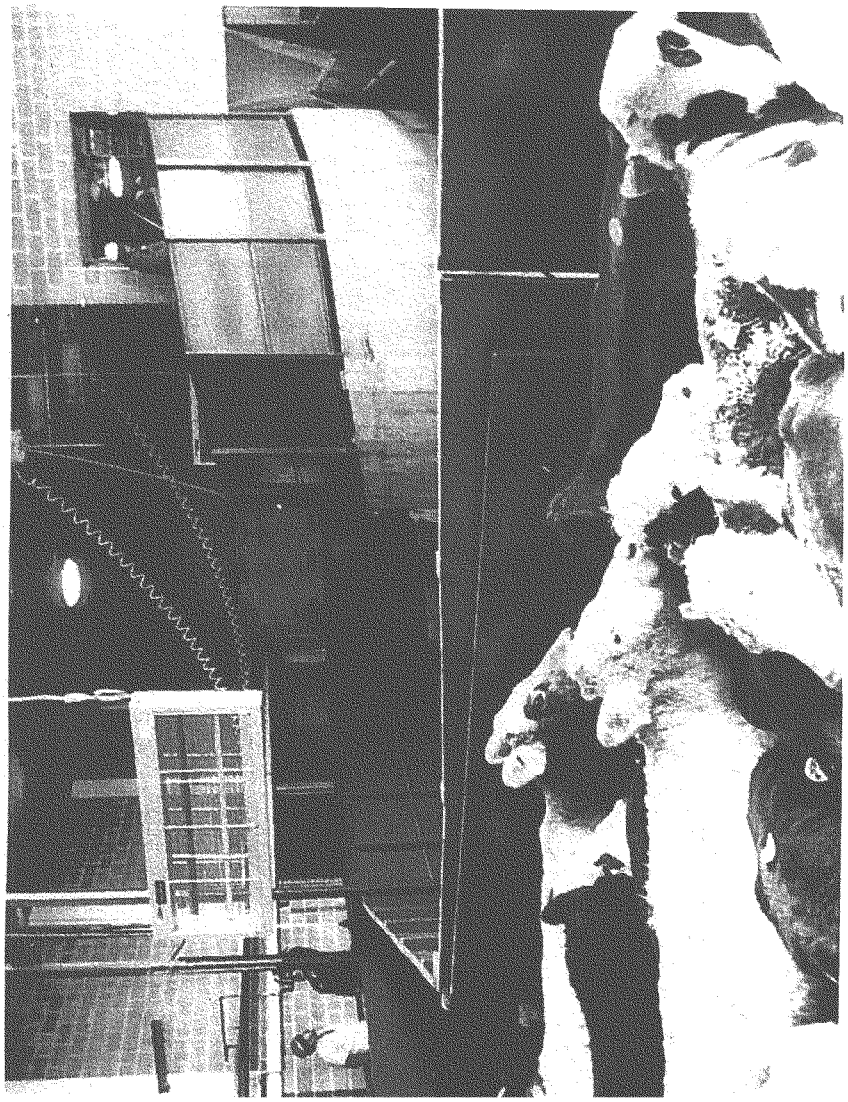
There is **Zero Tolerance** for **Skinning**, **Scalding**, **Dehairing** or **Removal of Any Body Part** on an Animal that Shows any Sign of Partial Return to **Sensibility**

Brain tissue contamination caused by stunning is low compared to spinal cord contamination caused by carcass splitting

Comparison of penetrating and non-penetrating captive bolt for CNS contamination measured by presence of marker protein or brain fragments in jugular vein blood

Penetrating	4% of cattle
Non-penetrating	2% of cattle

Coore et al., 2005



Splitting saw transfers of spinal tissue between carcasses

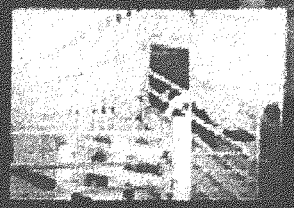
Helps et al., 2004

Smearing of spinal cord tissue due to splitting

Prendergast et al., 2003

Auditing of Cattle Truck Loading and Unloading Critical Control Points

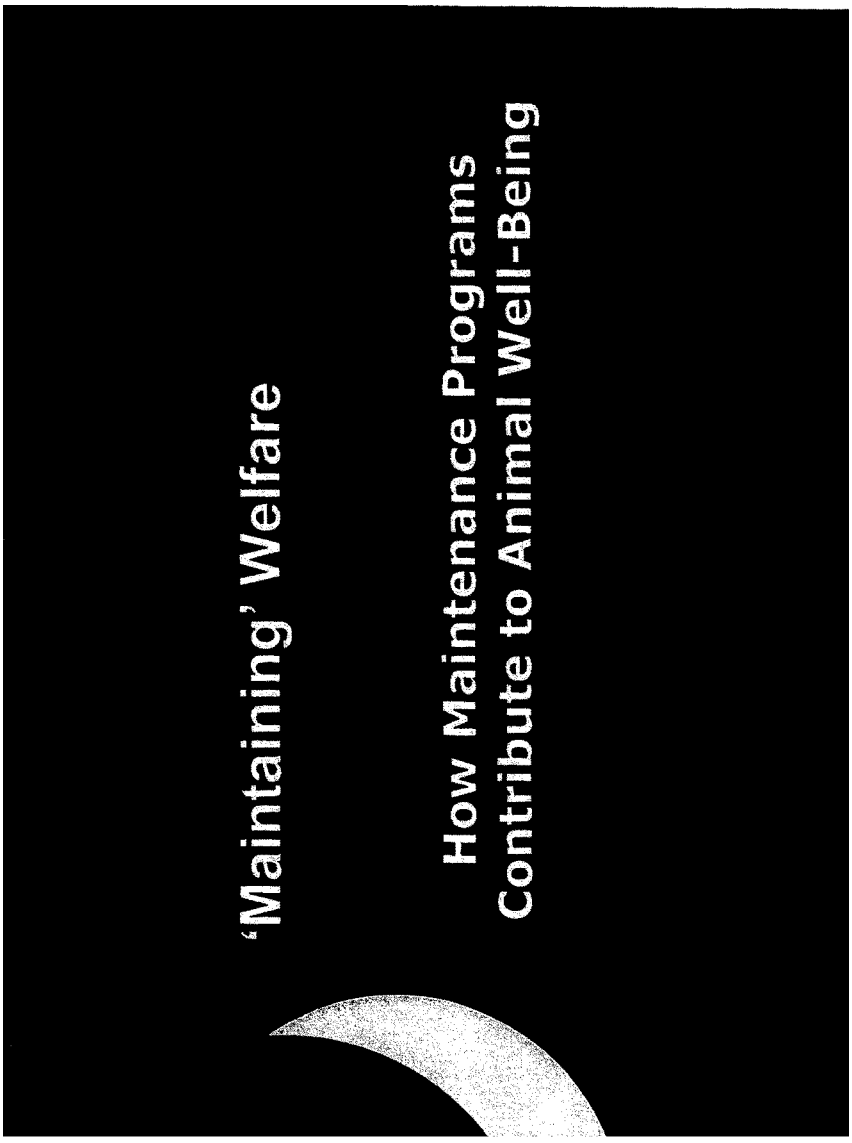
1. Falling Score - all falls are unacceptable
2. Speed Score -
   75% move at a walk or a trot
3. Electric Prod Score -
   5% or less are prodded
4. Striking Objects Score - 1% or less strike objects



Score each animal on a yes/no basis for each critical control point.

COMPARISON OF USDA SURVEY VOCALIZATION PERCENTAGES FOR 2002 AND 2003

	1996 before Restaurant Audits	2002	2003
Average Score	8 %	2 %	1.5 %
Worst Plant Score	35 %	6 %	7 %


'Maintaining' Welfare
How Maintenance Programs
Contribute to Animal Well-Being

We have an obligation to ensure that the well being of our animals is not compromised.

There are five basic causes of animal welfare problems in slaughter plants……

Good Maintenance Programs
will have an affect on the
basic causes.....
.....and will contribute
toward Animal Well-Being

1. Stressful equipment and methods.

2. Distractions that impede animal movement.

3. Lack of employee training.

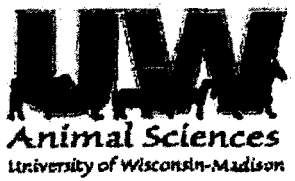
4. Poor equipment maintenance.

5. Condition of animals arriving at the plant.

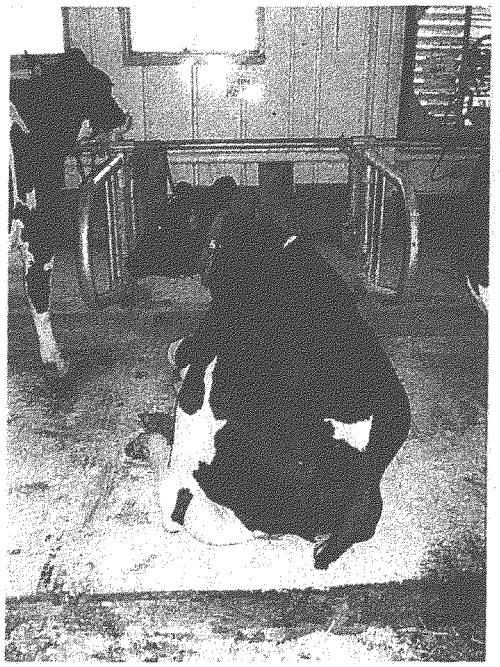
Developing A Good Maintenance
Program May Need A Culture Change !

Handling Challenges: **Cow Population**

Kurt Vogel
M.S. Student
Department of Animal Sciences
University of Wisconsin-Madison



The Dairy Cow



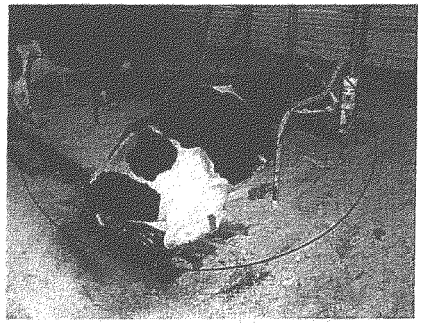
- Generally conditioned to handling
  - Smaller flight zone
- Calmer, more curious approach to novelty
- May have foot/leg soundness issues

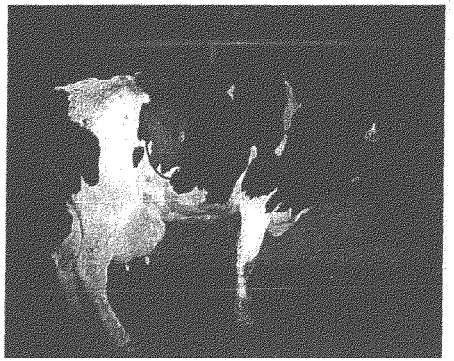
35.9% of dairy cows were culled due to Injury and Lameness from 1998 to 2001.

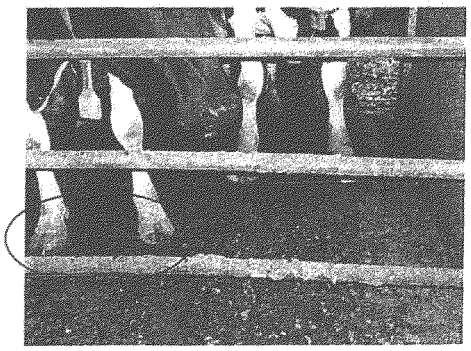
Source: "Do Dairy Producers Use Effective Management Practices to Improve the Value of Market Cows?" Tozer et al. 2005

Handling Issues Start at the Farm

- Problems:
  - Lameness
  - Compromised health
  - Temperament
- Solution:
  - Good Management!







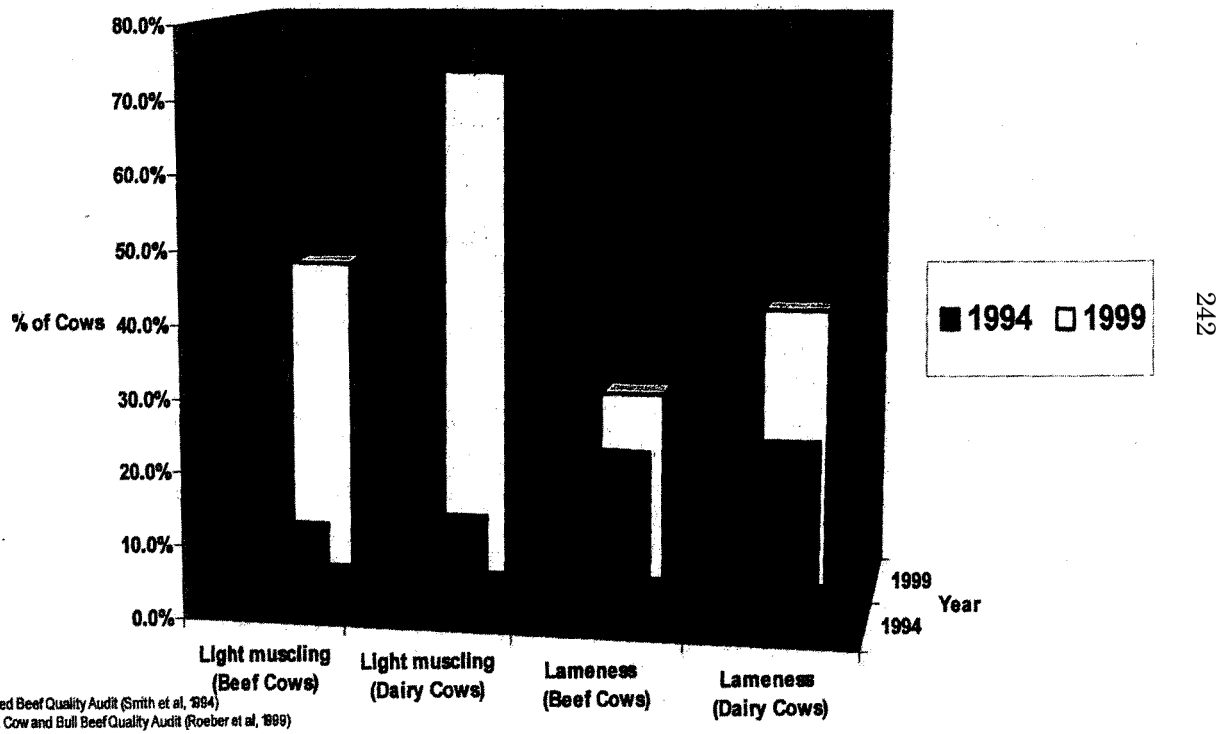
The Beef Cow

- Various levels of prior handling
- May tend to be more flighty and reactive to novelty
- May be more prone to temperament issues

The Agenda:

- **Handling Issues**
  - Farm
  - Trucking
  - Collection Point
  - Unloading
    - Non-Ambulatory Cattle
  - Holding and Staging Area
  - Serpentine and Restrainer
- **Handlers**
  - Good and Poor
- **Facilities**
  - Good characteristics
  - Deficiencies
- Case Study: Cargill Meat Solutions

Incidence of Light Muscling and Lameness in Cull Dairy and Beef Cows

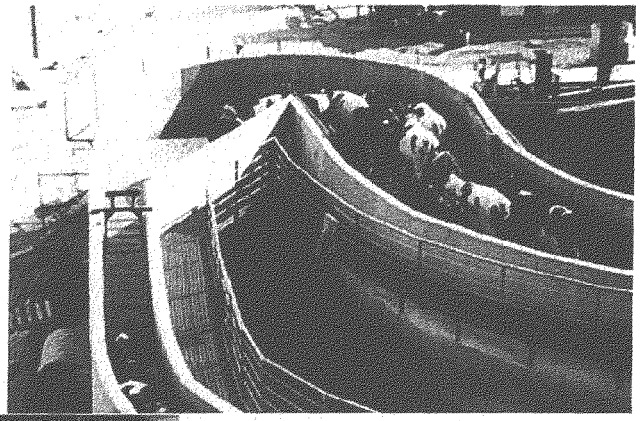


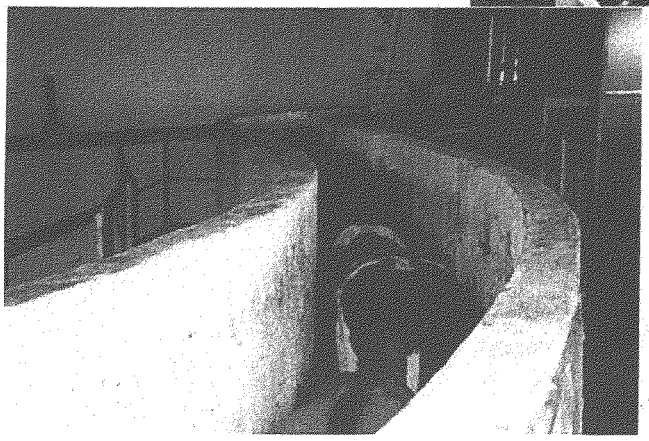
Sources: 1994 National Non Fed Beef Quality Audit (Smith et al, 1994)
1999 National Market Cow and Bull Beef Quality Audit (Roeber et al, 1999)

Issues at the Collection Point

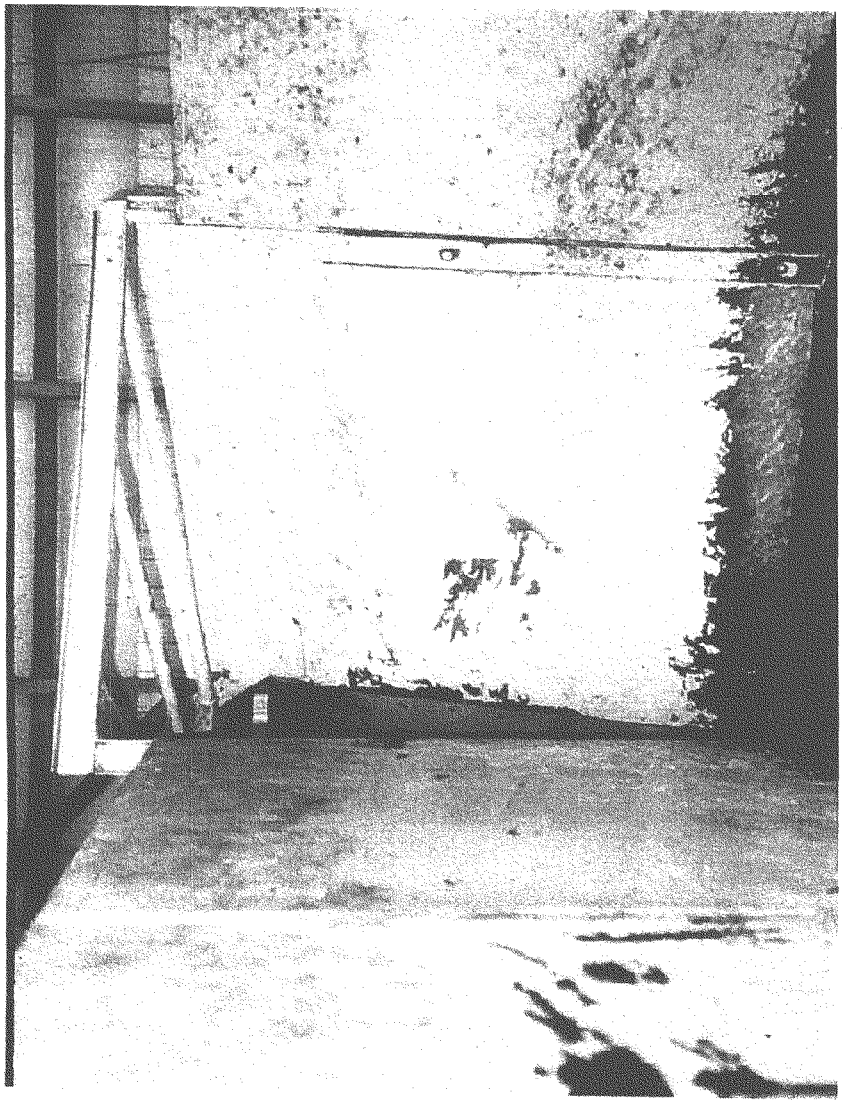
- Includes sale barns and buying stations
- May exacerbate existing conditions
  - Withdrawal from feed/water
  - Inadequate air quality
  - Rough handling
  - Overcrowding
- **Lack of accountability**
- **Plants can audit collection points!**

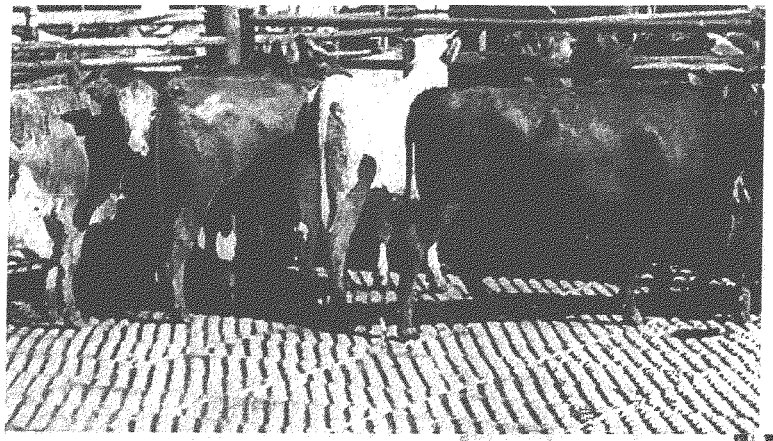
When Building New Facilities





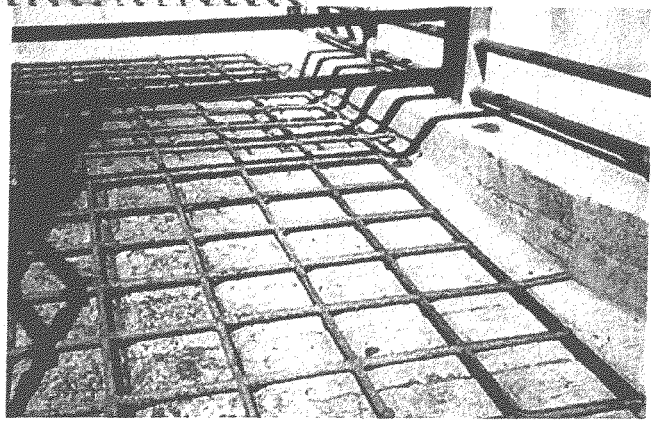
Curved Chutes with Solid Sides are Recommended





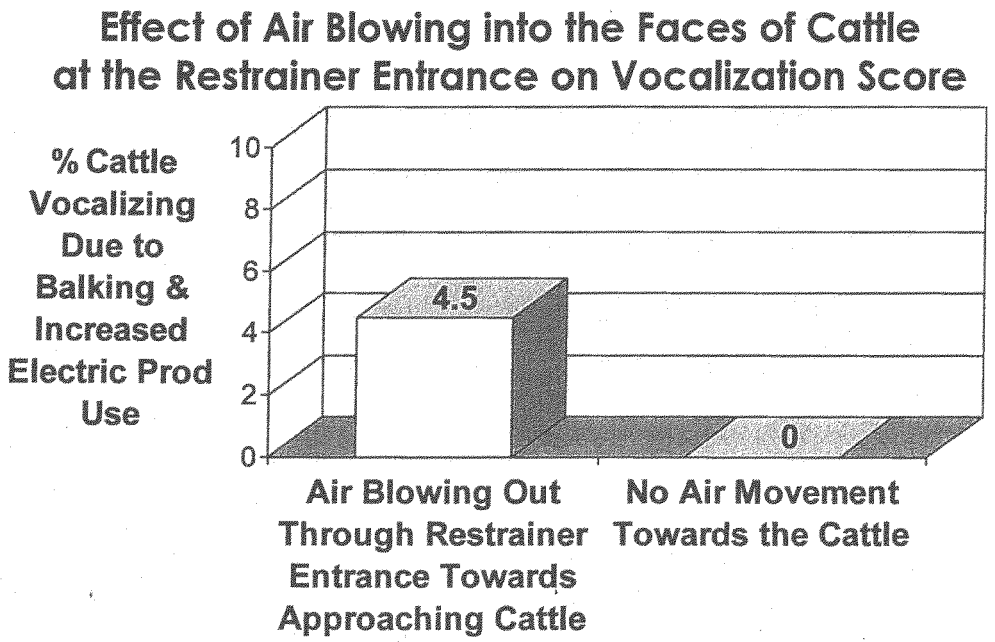
Non-slip Flooring is Essential

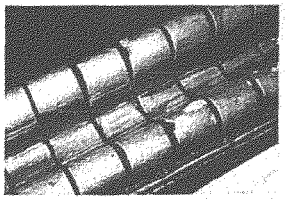
Audits Keep Finding Slick Floors



Scoring Can Also Be Used to Identify Hard to Handle Animals That May Cause Either Welfare or Meat Quality Problems

Use Scoring to Show How Changes Made in Your Operation Improved Handling





Causes of Increased Vocalization

1. Electric prod use
2. Missed stuns
3. Excessive pressure from restraint device
4. Sharp edges on restrainer devices
5. Isolated animal
6. Slipping

STUNNING CATTLE

2ND EDITION

Temple Grandin
Department of Animal Sciences
Colorado State University

Colorado State University
Knowledge to Go Places

Install Solid Sides and Shields to Block Vision

Points to consider

- Lighting
- Shadows
- Sunlight
- Color changes
- Reflections
- Floors
- Chases
- Fencing
- Gates
- Machinery noise
- People noise
- Air noise
- Air flow
- Smell
- Water
- Housekeeping
- Insensitivity

Affect sheet

Cattle affect sheet

	Slips and Falls	Bruising & cuts	Truck discomfort	Ease of movement	Lighting	Reflections /distractions	Sunlight /shadows	Machinery noise	Other noise	Air flow /smell	Insensibility issues
Outside areas			x								
Unloading area	x	x		x	x	x	x				
Cattle pens	x	x		x		x	x				
Walkways	x	x		x	x	x	x				
Crowd pen	x	x		x	x	x	x	x	x	x	
Lead up chute	x	x		x	x	x	x	x	x	x	
Restrainer area	x	x		x	x	x	x	x	x	x	
Stunning					x	x		x	x		x

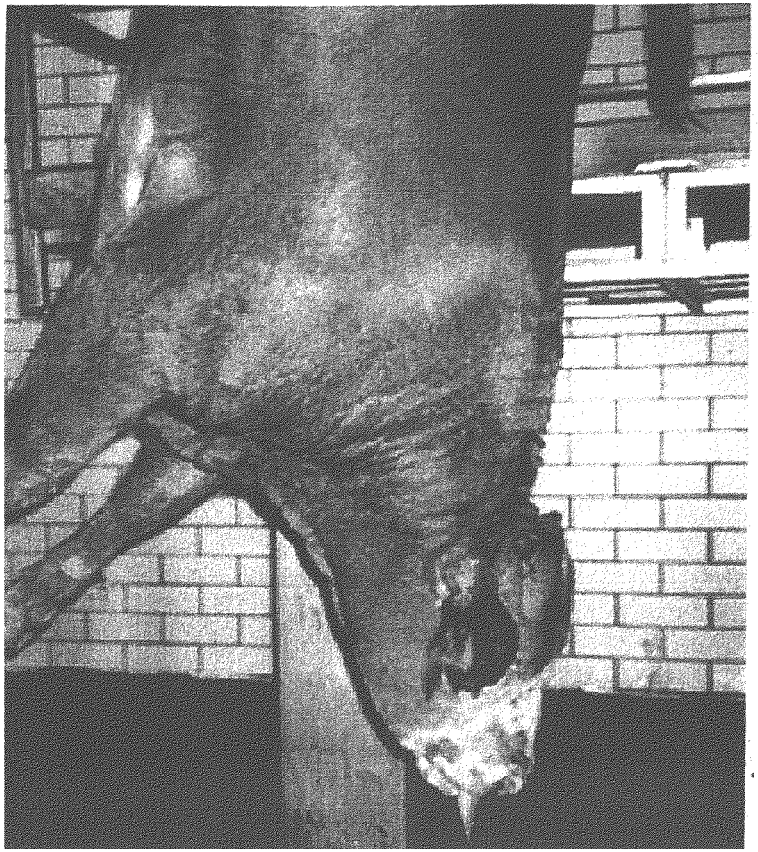
Truck discomfort.	Large potholes in the road, excessive bumps.
Slips and falls.	Condition of floors, non slip design, housekeeping, wear.
Bruising and cuts.	Sharp edges, damaged fencing, protrusions,narrow entrances, sharp turns, obstructions.
Ease of movement.	Turn radius, obstructions
Lighting.	Not too bright. Directional lighting to illuminate ahead of cattle. No light directly at cattle. Illuminate above stun area.
Reflections/distractions.	Shiny chains, flapping materials, bright color differences, people
Sunligh/shadows.	Look for brigh/dark spots during different times of suuny days.
Machinery noise.	Motor whie, pneumatic venting, hydraulic hum, conveyors moving.
Other noise.	Loud bangs, gate noises, outside distractions (construction etc.)
Air flow/smell.	No air flow from restrainer area.
Insensibility.	Stunning equipment verification. Observe bleed rails.

AMI Handling guidelines 2005 Visual observations of cattle behaviour Equipment handbooks

Cartridge
Fired
Stunner
Must keep
cartridges dry

Stunning equipment

- The stunning equipment is a critical link in the process
- The stunner delivers a fixed weight bolt at the proper velocity to achieve an effective stun.
- Good stunner maintenance is an important element of humane slaughter
- Diagnostic tools help evaluate equipment performance



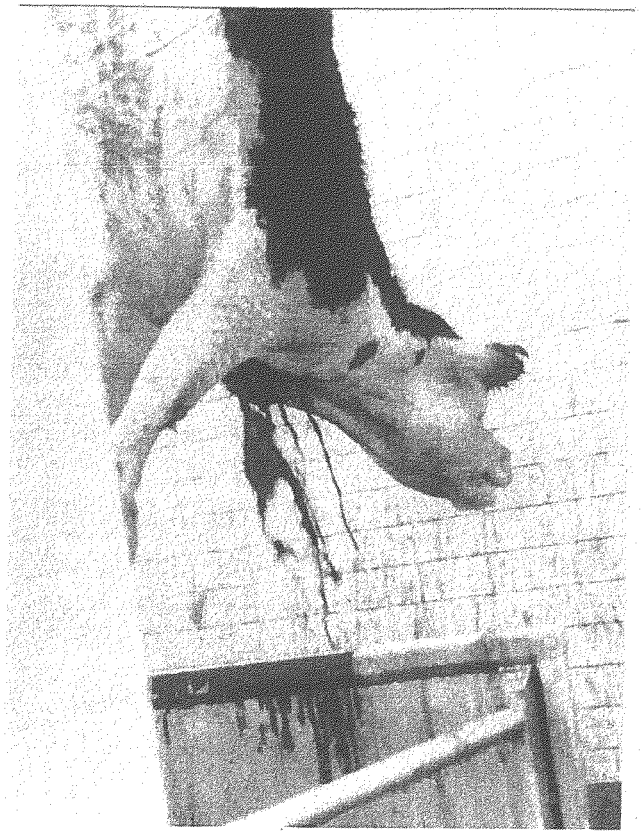
Correctly Stunned Animal

Completely insensible

INSENSIBILITY

- No blinking
- No arched back, righting reflex
  (small side flex is permissible)
- No breathing
- Floppy head
- No nose movements "rabbit nose"
- Limp flaccid tongue
  (may be trapped in the mouth of a properly stunned animal)

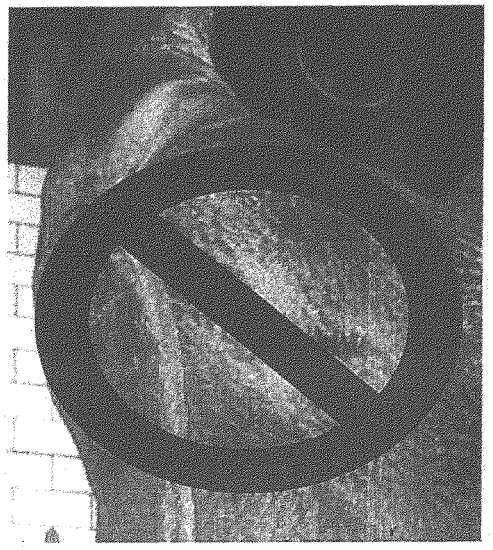
Checking for breathing by holding the nose

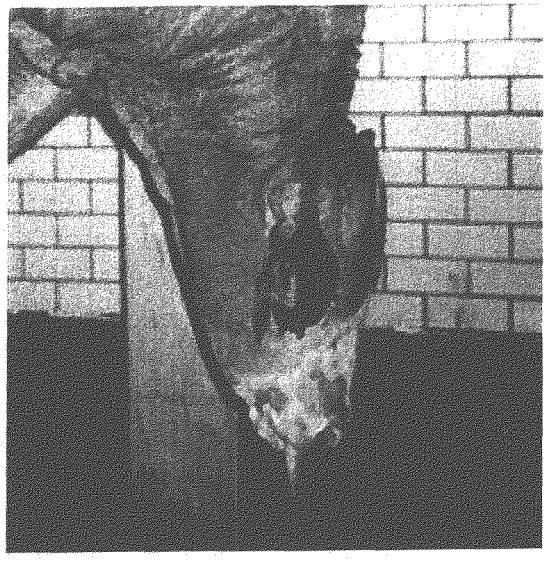


Sensible bovine with righting reflex

(photo not from U.S.)

Head must be Dead!!!





Ignore the Body

It is normal to have kicking in a correctly stunned animal

Handler Education

- Yearly training of cattle haulers.
- Annual or bi-annual training of employees.
- Gives plant a chance to lay out guidelines and rules.
- Gives haulers and handlers a chance to offer feedback.

Study your plant!

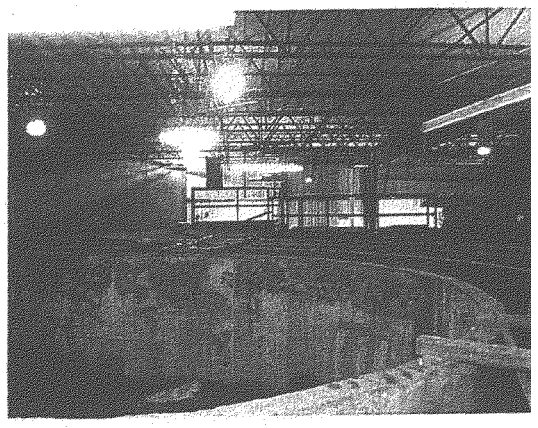
- Monitor changes in harvest efficiency
- Perform regular facility walkthroughs
- Observe at a distance when possible
- Experiment, experiment, experiment!
- Maintain open communication with other plants.

Issues in facility deficiencies

- Upgrades can be expensive!
  - Lost time
  - Materials and labor
- The success of major changes is not guaranteed!
  - Experiment with lower cost solutions first.

Lighting

- Added Lights to area above serpentine
- Goal of reducing shadows and improving flow
- Created "open door effect" through light placement on corners.



Cargill

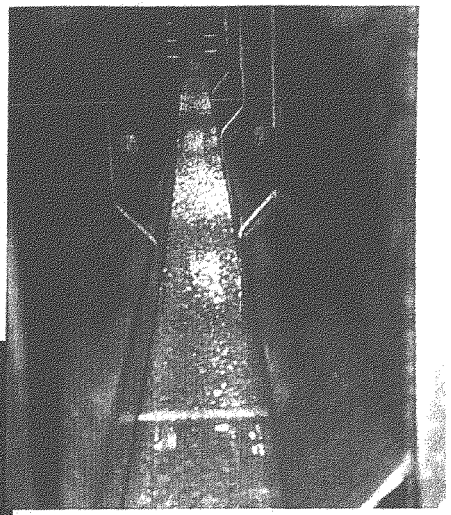
Characteristics of a good cow plant

- Fairly level layout
- Good footing
- Good lighting
- Low noise
- Consistent atmosphere
- **Proactive management**

Attributes of a poor cow handler

- Impatient
- Combative
- Violent
- Loud
- Stubborn
- Argumentative

Reflections on a Wet Floor



Balking Scores

Low Balking Plant (well-trained handlers)		High Balking Plant (facility problem)	
% Cattle Backing Up in the Chute	% Vocalizing	% Cattle Backing Up in the Chute	% Vocalizing
0%	1%	38%	8%
3%	2%	25%	8%

Vocalization Score Increase Due to Increased Electric Prod Use

Cattle can
see these
boots
through
the grating

Cattle may
refuse to
walk over
drain

On a sunny day
cattle may refuse to
enter a dark building

Identify the distractions in these photos

Be
Observant:
What distraction would cause balking
in this photo?

Light up a dark entrance to
reduce balking

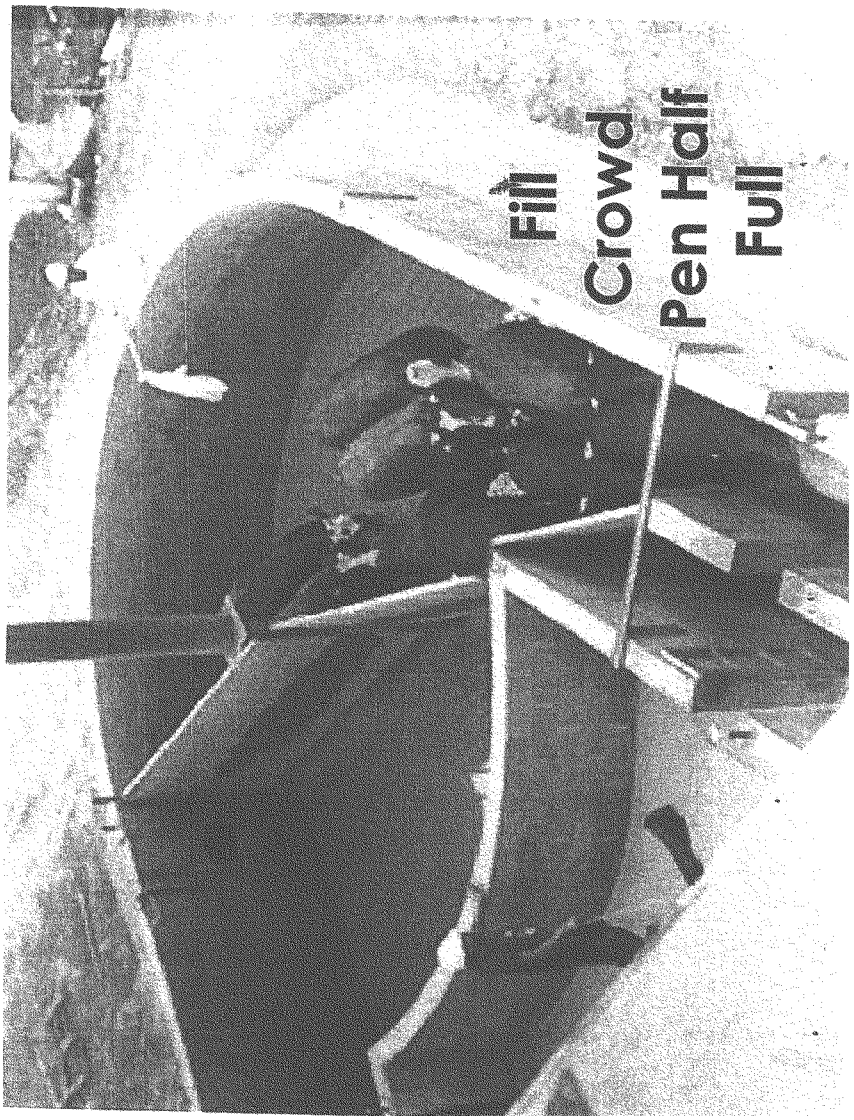
Facility "A" Master location list

Location Description	location #	Sub location	location #	Sub location	location #
Outside area	001	Roadways and walkways	001-RW		
		Fencing and gates	001-FG	North Fencing	001-FG-N
				South Fencing	001-FG-S
		Lighting	001-LTG		
		Tool storage shed	001-TSS		
		Sawdust storage	001-SDS		
Cattle receiving area	002	level docks	002-LD	Level dock 1	002-LD1
				Level dock 2	002-LD2
				Level dock 3	002-LD3
		Unloading Ramps	002-UR	Unloading ramp 1	002-UR1
				Unloading ramp 2	002-UR2
				Unloading ramp 3	002-UR3
		Unloading pens	003-UP	Unloading pen 1	002-UP1
				Unloading pen 2	002-UP2
				Unloading pen 2	002-UP3
Barn (building)	004	Barn structural	004-BS		
		Barn infrastructure	004-BI		
		Barn electical	004-BE		
		Barn ventilation	004-BA		
Cattle Pens	003	Cattle Pen 1	003-CP1		
		Cattle Pen 2	003-CP2		
		Cattle Pen 3	003-CP3		
		Cattle Pen 4	003-CP4		
		AND SO ON			
Crowd pen	005				
Lead up chute	006				
Restrainer area	007				
Stunning	008				
Handling equipment	009				

Contrast of
light and dark
attracts the
animal's
attention

Handler Movement Pattern to Keep Cattle Moving
Into a Squeeze Chute or Restrainer
Return path leaving flight zone.
Path to move animals forward.
Squeeze
Chute
Point of
Balance
Cattle will move forward when the handler passes
the point of balance at the shoulder of each
animal. The handler walks in the opposite
direction along side the single file race.

Using the right zone correctly to
control cattle movement


Fill
Crowd
Pen Half
Full

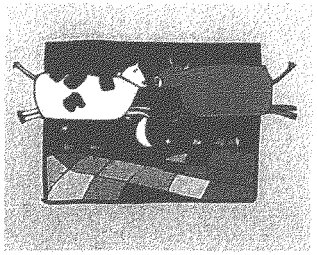
Handler Movement Pattern to Keep Cattle Moving
Into the Squeeze Chute in a Curved Chute System
Point of
Balance
Cattle will move forward when
handler crosses the point of
balance of each animal.
Squeeze
Chute
Crowd
Pen

Alternative
Driving Aids

Move in Small Groups

You Manage What You Measure

Track whether or not you improve or get worse



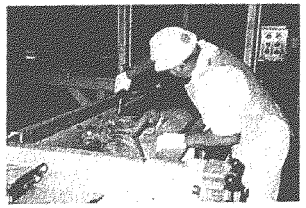
Easy Fixes to Reduce Balking

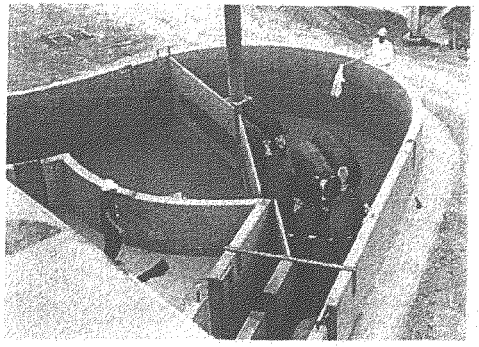
1. Hang a curtain in front of the restrainer
2. Move a ceiling light to eliminate a reflection on wet shiny surfaces
3. Change color of employee hats or coats to reduce contrast
4. Change where people stand
5. Experiment, Experiment with lights
6. Flooring in crowd pens and chutes should look the same

AMI
SCORING SYSTEM

Stunned with one shot	95%
Insensible	100%
Electric prod	25%
Falling down	1%
Vocalizing	3%

AMERICAN MEAT INSTITUTE





Tips for Handling

1. Move in <u>small bunches</u>
2. The crowd pen is the "passing through pen"
   (Do not let animals stand in it)
3. Timing of bunches so animals <u>keep moving</u>
4. Fill the crowd pen <u>half full</u>
5. Do not push animals with the crowd gate

HANDLING AUDITS

Percentage of Cattle Vocalizing		Number of Plants	Percentage of Plants
➢0 to 1 %	(Excellent)	30	60 %
➢2 to 3 %	(Acceptable)	13	26 %
➢4 to 5 %	(Borderline)	6	12 %
➢6 to 10 %	(Fail)	1	2 %
➢Over 10 %	(Fail)	0	0 %

HANDLING AUDITS

Percentage of Cattle Electric Prodded		Number of Plants	Percentage of Plants
➢0 to 5 %	(Excellent)	30	60 %
➢6 to 25 %	(Acceptable)	15	30 %
➢Over 25 %	(Fail)	2	4 %
➢Poked sensitive part of the animal.		3	6 %

Affidavit of Pablo Salas

State of California)
)
County of San Bernardino)

I, Pablo Salas, hereby swear, deposes and says:

1. For all relevant times referenced herein, I was the Plant Manager of Hallmark Meat Company, principally responsible for, among other things relating to the harvesting operation, the human treatment of the cattle .

2. I have personal knowledge of all the herein attested to facts.

3. Once every year I conducted an annual training session concerning the humane treatment of the cattle. This training session lasted approximately 45 minutes to one hour and was done in English and Spanish. It was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark attend such meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting

4. In October of 2006 and again in October 2007, I conducted such annual training sessions

5. In addition to the annual training sessions, a monthly training session was conducted. These monthly sessions were for the purpose of reinforcing the originally taught procedure and to introduce any new procedures for the humane treatment of the cattle. Each such monthly training session typically lasted 15 - 30 minutes and again were all conducted in both English and Spanish. Like the annual meeting, it was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark, attend these monthly meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting.

6. I personally conducted these monthly sessions in February, March, April, May and June of 2007.

7. The Monthly Training session in November , 2007 was conducted by the Harvest Floor Foreman, Gustavo Manzo. He also assisted me in conducting the February 2007 meeting (See Affidavit of Gustavo Manzo).

8. The Monthly Training sessions in July August and September, 2007 were conducted by the Quality Control Supervisor, Martin Laguna

The Monthly Training session for January was conducted by both Martin Laguna and the Pen Supervisor, Daniel Ugarte. (See Affidavit of Martin Laguna)

9. The Monthly Training sessions in December, 2007 was conducted by the Pen Supervisor, Daniel Ugarte.

Executed on this 24 day of April, 2007, in the City of Chino, County of San Bernardino, State of California

Pablo Salas

Pablo Salas

Affidavit of Gustavo Manzo

State of California)
)
County of San Bernardino)

I, Gustavo Manzo, hereby swear , deposes and says:

1. For all relevant times referenced herein, I was the Harvest Floor Supervisor of Hallmark Meat Company.

2. I have personal knowledge of all the herein attested to facts.

3. Once every year Hallmark conducted an annual training session concerning the humane treatment of the cattle. This training session lasted approximately 45 minutes to one hour and was done in English and Spanish. It was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark attend such meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting

4. In October of 2006 and again in October 2007, The Plant Manager of Hallmark, Pablo Salas, conducted such annual training sessions

5. In addition to the annual training sessions, a monthly training session was conducted. These monthly training session lasted 15 -30 minutes and were all conducted in both English and Spanish. Like the annual meeting, it was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark, attend these monthly meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting.

6. I personally conducted the monthly training session in November , 2007 and assisted Mr. Salas in conducting the February, 2007 training session.

Executed on this 24 day of April, 2007, in the City of Chino, County of San Bernardino, State of California

Gustavo Manzo

Affidavit of Martin Laguna

State of California)
)
County of San Bernardino)

I, Martin Laguna, hereby swear , deposes and says:

1. For all relevant times referenced herein, I was the Quality Control Supervisor for Hallmark Meat Company.

2. I have personal knowledge of all the herein attested to facts.

3. Once every year an annual training session concerning the humane treatment of the cattle was conducted by Hallmark. This training session lasted approximately 45 minutes to one hour and was done in English and Spanish. It was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark attend such meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting

4. In October of 2006 and again in October 2007, The Plant Manager of Hallmark, Pablo Salas, conducted such annual training sessions

5. In addition to the annual training sessions, a monthly training session was conducted. These monthly training session lasted 15 -30 minutes and were all conducted in both English and Spanish. Like the annual meeting, it was mandatory that each and every Hallmark employee who in any way worked around and or with the live cattle delivered to Hallmark, attend these monthly meetings and were thereafter required to execute an acknowledgment that they in fact attended the meeting.

6. I personally conducted the monthly training session in January, July, August and September 2007.

Executed on this 24 day of April, 2007, in the City of Chino, County of San Bernardino, State of California

Martin Laguna

Martin Laguna

Safety Meeting

COMPANY Hallmark Meat Packing CO. | DATE 01-19-07

LOCATION / DEPT. / SITE | TIME / SHIFT 6:00/am

Topic Humane Handling

How to unload cattle from the trucks with out using the electric. prod.

Supervisor Marton Laguna

EMPLOYEES ATTENDING:

Juan Campos P
David Ugarte
Guillermo Ruiz
Luis Sanchez
Lusio Rivera

Safety Meeting

COMPANY: Hallmark Meat Packing Co.
DATE: 02-16-07
LOCATION / DEPT. / SITE: Cattle Receiving Office
TIME / SHIFT: 6:15/am

Topic: HUMANE HANDLING

Unloading disable cattle.

Supervisor: [signature]

EMPLOYEES ATTENDING:

Guillermo Ruiz
Luis Sanchez
Daniel Ugate
Juan Campos
Julio Rivera.

HALLMARK MEAT COMPANY ESTABLISHMENT #336

HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

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HALLMARK MEAT COMPANY

Guillermo Ruiz 02-09-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 02-09-07
Trainer's Name and Signature Date

TRADE SECRET CONFIDENTIAL INFORMATION

(Upon completion of this form please forward it to Pablo Salas)

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HALLMARK MEAT COMPANY

Luis Sanchez 020907
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 020907
Trainer's Name and Signature Date

TRADE SECRET CONFIDENTIAL INFORMATION

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HALLMARK MEAT COMPANY

Daniel Wright 02-09-07
Employee's Printed Name and Signature Date

PABLO SALAS Pablo Salas 02-09-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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HALLMARK MEAT COMPANY

Juan Campos 02-09-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 02-09-01
Trainer's Name and Signature Date

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HALLMARK MEAT COMPANY

J. Julio Rivera. 02-09-07

Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 020907

Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez
Employee's Printed Name and Signature Date 3-16-07

PABLO SALAS Pablo Salas 3/16/07
Trainer's Name and Signature Date

TRADE SECRET CONFIDENTIAL INFORMATION

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13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

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WESTLAND/HALLMARK MEAT COMPANY

David Wright 3-16-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 3/16/07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Martin Perez Mar 2-16-007
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 3/16/07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Antonio M. Rocha, Antonio M. Rocha 3-16-07

Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 3/16/07

Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

LUIS AYON 3/16/07

Employee's Printed Name and Signature Date

P.S. LUIS Pablo Salas Pablo Salas 3/16/07

Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos Perez Juan Campos P.
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 3/14/07
Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO RUIZ 03-16-07
Employee's Printed Name and Signature Date

PABLO SALAS Pablo Salas 3/16/07
Trainer's Name and Signature Date

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HALLMARK MEAT COMPANY

David Negrete 04-11-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 04-11-07
Trainer's Name and Signature Date

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HALLMARK MEAT COMPANY

Luis Sanchez 04/11/07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 04-11-07
Trainer's Name and Signature Date

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Luis Rivera 04/11/07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 04-11-07
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Juan Campos 04-11-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 04-11-07
Trainer's Name and Signature Date

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Guillermo Ruiz 04-11-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 04-11-07
Trainer's Name and Signature Date

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Guillermo Ruiz 05-14-07
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Pablo Salas Pablo Salas 05-14-07
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Pablo Salas Pablo Salas 05-14-07
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HALLMARK MEAT COMPANY

Lucio Rivera. 05-14-07

Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 05-14-07

Trainer's Name and Signature Date

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HALLMARK MEAT COMPANY

Daniel Ulloa 05-14-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 05-14-07
Trainer's Name and Signature Date

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HALLMARK MEAT COMPANY

Luis SanCHEZ 05-14-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 05-14-07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Martin Perez 060608
Employee's Printed Name and Signature Date

Pablo Salas 6-06-07
Trainer's Name and Signature Date

TRADE SECRET

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13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

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WESTLAND/HALLMARK MEAT COMPANY

Lucio Rivera Lucio Rivera 05-06-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 6-06-07
Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos Juan C. 060608
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 6-06-07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Juan Jaramillo 06/06/07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 6-06-07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO R 01-06-07

Employee's Printed Name and Signature Date

Maria Lagunas 01-06-07

Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos 07-06-07
Employee's Printed Name and Signature Date

Martin Iglesia 07 06 07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Daniel Zepeda 07-0607
Employee's Printed Name and Signature Date

Marlon Lagunas 07-0607
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 07-06-07
Employee's Printed Name and Signature Date

Makin Lagma 07-06-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

Safety Meeting

COMPANY Hallmark Meat Packing CO. | DATE 08-09-07

LOCATION / DEPT. / SITE | TIME / SHIFT 3:15/pm

Topic ~~Humane~~ Handling

How to handle disable ~~ex~~ cattle

Supervisor Martin Laguna

EMPLOYEES ATTENDING:

- Luis Sanchez
- Juan Campos P.
- Daniel Iguarta
- Lusio Rivera
- Guillermo Ruiz

WESTLAND/HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO R 08-16-07
Employee's Printed Name and Signature Date

Martin Vegas 08-16-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 08-16-07
Employee's Printed Name and Signature Date

Martin Lagma 08-16-07
Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Daniel Negrete 08-16-07
Employee's Printed Name and Signature Date

Martin Lagunas 08-16-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos 08/16/07
Employee's Printed Name and Signature Date

Martin Vazquez 08/16/07
Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO R 09-24-07
Employee's Printed Name and Signature Date

Martin Segura 09-24-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION TRADE SECRET

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13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos 09-24-07
Employee's Printed Name and Signature Date

Marlen Laguna 09-24-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Daniel [illegible] 09-2407
Employee's Printed Name and Signature Date

Martin Lagoma 092407
Trainer's Name and Signature Date

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 09-24-07
Employee's Printed Name and Signature Date

Martin Iniguez 092407
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION TRADE SECRET

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REVISED MARCH 2005

HALLMARK MEAT COMPANY ESTABLISHMENT #336

HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

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HALLMARK MEAT COMPANY

Sean Thomas Seitz 10-3-07
Employee's Printed Name and Signature Date

Pablo Salas Pablo Salas 10-03-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO Ruiz 10807
Employee's Printed Name and Signature Date

Jose Gustavo Mata Jose Gustavo Mata 10-08-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Martin Perez 10807
Employee's Printed Name and Signature Date

Jose Gachuo Marco 10-08-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Sean Thomas 10-8-07

Employee's Printed Name and Signature Date

Jose Gustavo Mata 10-8-07

Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Daniel Negrete 10-08-07
Employee's Printed Name and Signature Date

Jose Gustavo Ramos Jose Gustavo Ramos 10-08-07
Trainer's Name and Signature Date

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 10-08-07
Employee's Printed Name and Signature Date

Jose Gustavo Munoz 10-08-07
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos Juan R Campos 10-08-07
Employee's Printed Name and Signature Date

Jose Gustavo Munoz Jose Gustavo Munoz 10-08-07
Trainer's Name and Signature Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Cecilio Campos — 10/08/07
Employee's Printed Name and Signature / Date

Jose Gutierrez Marco — 10/08/07
Trainer's Name and Signature / Date

CONFIDENTIAL INFORMATION

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Employee's Printed Name and Signature — Date

Trainer's Name and Signature — Date

TRADE SECRET

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WESTLAND/HALLMARK MEAT COMPANY

Sean Thomas _____ Nov 12 / 07
Employee's Printed Name and Signature Date

Jose Gustavo Mpnzo _____ 11/12 07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Martin Perez 11-12-07
Employee's Printed Name and Signature Date

Jose Gustavo Marco 11-12-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 11-12-07
Employee's Printed Name and Signature Date

Jose Gustavo Marzo Jose Gustavo Marzo 11/12/07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Daniel Agustin 11-12-07
Employee's Printed Name and Signature Date

Jose Gustavo Mares Jose Gustavo Mares 11/12/07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Juan R. Campos Juan Campos 11-12-07
Employee's Printed Name and Signature Date

Jose Gustavo Monzo Jose Gustavo Monzo 11-12-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL REPRESENTATION

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

HALLMARK MEAT COMPANY ESTABLISHMENT #336

HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

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HALLMARK MEAT COMPANY

Cecilio Campos 11/12/07
Employee's Printed Name and Signature Date

Jose Gustavo Munoz 11/2/07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Cesar Mosqueda C. M. 11-7-07
Employee's Printed Name and Signature Date

Jose Gustavo Mora Jose Gustavo Mora 11-2-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Jesus Acosta Jesus A. 11.12.07
Employee's Printed Name and Signature Date

Jose Gustavo Mata Jose Gustavo Mata 11-12-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

GUILLERMO 12-03-07
Employee's Printed Name and Signature Date

David Wyatt 12-03-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Marilyn Perez 12-03-01
Employee's Printed Name and Signature Date

David Ugarte 12-03-01
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL

(Upon completion of this form please forward it to Pablo Salas)

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

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WESTLAND/HALLMARK MEAT COMPANY

Juan Campos P. Juan P. Campos Perez 12/03/07
Employee's Printed Name and Signature Date

David Vigueta 12/03/07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

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WESTLAND/HALLMARK MEAT COMPANY

Cecilio Campos 12-03-07
Employee's Printed Name and Signature Date

David Ugarte 12-03-07
Trainer's Name and Signature Date

TRADE SECRET

CONFIDENTIAL INFORMATION

(Upon completion of this form please forward it to Pablo Salas)

13677 YORBA AVENUE CHINO CALIFORNIA 91710

REVISED MARCH 2005

WESTLAND/HALLMARK MEAT COMPANY ESTABLISHMENT #336

WESTLAND/HALLMARK MEAT COMPANY

HUMANE HANDLING AND HARVESTING OF LIVESTOCK TRAINING FORM

By signing below, I understand all policies and procedures that involve the Humane Handling and Harvesting of cattle (both ambulatory and non-ambulatory) at Westland/Hallmark Meat Company (WHMC). I have been instructed and trained regarding my job assignment(s) as documented in our written program.

I also understand that if I have any questions regarding the strict requirements of this program with regards to my assigned job(s) or that of others, I have been instructed and understand fully that I am to notify my direct Supervisor immediately.

WESTLAND/HALLMARK MEAT COMPANY

Luis Sanchez 01-09-08
Employee's Printed Name and Signature Date

Daniel Vizcarra 010908
Trainer's Name and Signature Date

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WESTLAND/HALLMARK MEAT COMPANY

Cecilio Campos 01/09/08
Employee's Printed Name and Signature Date

David Urgiste 01-09-08
Trainer's Name and Signature Date

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